

Papilla cannulation in ERCP through remote or in-person training: study protocol for a single-centre randomised controlled trial (SmartERCP-Trial)”

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Abstract

Background

Endoscopic retrograde cholangiopancreatography (ERCP) is a complex procedure requiring specialised training and guidance. Due to the shortage of medical specialists and limited training capacities, it is not always possible to arrange training in the presence of a trainer or to transfer a patient to a specialist hospital immediately. Therefore, this study aims to investigate whether teaching with smart glasses via telemedicine is just as effective and safe as teaching in person.

Methods

The study is a prospective, randomised, non-inferiority trial, with the primary endpoint being the time taken to cannulate the native papilla. Based on previous studies, it can be assumed that trainee physicians will successfully cannulate the papilla 70% of the time, with an average cannulation time of 8.8 minutes (± 11.9 minutes SD). The experimental method is defined as non-inferior if the extension to the cannulation time is 5 minutes or less than in the standard method. With a statistical power of at least 80%, a one-sided P-value of 0.05, and an expected dropout rate of 10% per study arm, the required sample size is $n = 85$ per study arm. An important safety measure is that the instructor will provide guidance on a computer screen in an adjacent room and can switch to the instructor-in-attendance position at any time. Ethics approval (A 2024 – 0212) for the study was provided by the Rostock University Medical Centre on 11 December 2024.

Discussion

The strength of this study design lies in its prospective, randomised design, which focuses on a central, precisely measurable competence: the time taken to cannulate the native papilla during ERCP. Potential limitations in the evaluation might include an increased conversion rate from telemedical guidance to in-person guidance from the instructor, and an imbalanced level of difficulty for ERCP in both randomised groups.

Trial registration

ClinicalTrials.gov number NCT06683716

Administrative information

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

Title {1}	A Randomized Controlled Trial Comparing Telemedical Assistance via Smart glasses to Physical Presence in ERCP Training
Trial registration {2a and 2b}.	ClinicalTrials.gov ID: NCT06683716
Protocol version {3}	Protocol Version 3.0, dated 3 August 2026
Funding {4}	No external funding was received. This study is conducted using institutional (in-kind) resources of Helios Kliniken Schwerin, the employer of the investigators, which provides facilities, staff time and organisational support necessary for the conduct of the trial; no additional financial sponsorship was received.
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Name and contact information for the trial sponsor {5b}	Helios Kliniken Schwerin Schwerin, Mecklenburg-Vorpommern, Germany, 19055 Contact: Jörg-Peter Ritz (Medical director of the whole hospital), Prof. Dr. med. +49-385-520-2050 Joerg-Peter.Ritz@helios-gesundheit.de
Role of sponsor {5c}	The sponsor, Helios Hospital Schwerin, provides facilities, resources, and organizational support for the study. The sponsor is not involved in the study design, data collection, analysis, interpretation of results, or the decision to submit the report for publication. The principal investigator, Dr. med. Daniel Schmitz, oversees the study and is responsible for its execution.

Introduction

Background and rationale {6a}

Endoscopic retrograde cholangiopancreatography (ERCP) is a technically challenging procedure that requires significant expertise to ensure successful outcomes and minimise risk to patients [1]. A key skill in ERCP is endoscopic papilla cannulation, which is essential for accessing the bile or pancreatic ducts [2]. However, outside regular working hours and in sparsely populated regions or areas with a shortage

of experienced ERCP specialists, it may not be possible to have an experienced examiner present. Therefore, telemedical examination assistance via a connection to data glasses worn by the examiner is a possible alternative [3]. Despite its promise, the safety and efficiency of this approach in the context of ERCP training remain unproven. While telemedicine has proven useful in other medical disciplines, its application in challenging endoscopic procedures such as ERCP has yet to be demonstrated. This study therefore aims to address this gap by evaluating whether telemedical assistance using smart glasses can match the effectiveness of a physical presence in terms of procedure success and safety. The results of this trial could support the integration of telemedical solutions into ERCP training, potentially improving access to high-quality instruction in underserved areas.

Objectives {7}

The primary objective of this study is to evaluate whether telemedical assistance via smart glasses is not inferior to physical presence in the teaching of endoscopic retrograde cholangiopancreatography (ERCP).

Trial design {8}

This study is a **prospective, parallel group, randomized controlled trial** with the aim at comparing two methods of teaching **endoscopic retrograde cholangiopancreatography (ERCP)**. The participants will be **randomly assigned** to one of the two groups in a **1:1 allocation ratio**.

In Group 1 (Active Comparator), the participants (trainee physicians) will receive the ERCP training in the presence of an experienced instructor in the examination room.

In Group 2 (Experimental: Telemedical Training), participants (trainee physicians) will receive training with telemedical assistance, from an instructor via smart glasses.

The primary objective of this study is to evaluate whether smart glasses based telemedical assistance is **non inferior** to the physical presence of an instructor regarding successful and safe **papilla cannulation** during ERCP training. The design of the study aims to demonstrate that telemedical assistance via smart glasses can be an effective and safe alternative to in-person instructor-led training.

Methods: Participants, interventions and outcomes

Study setting {9}

The study will be conducted at the Helios Kliniken Schwerin, University Campus of Medical School Hamburg, Schwerin, Germany. Data collection will take place at this location.

Eligibility criteria {10}

Physicians who have completed their internal medicine residency or are currently training to become a gastroenterologist are eligible trainees. Eligible trainees may also include gastroenterology fellows still

being trained to perform ERCP, such as senior fellows or attending physicians who need occasional assistance. Physicians, who have not completed internal medicine residency, will be excluded. ERCP trainers are chosen from among gastroenterologists with more than 10 years' experience performing ERCPs and a regular caseload of more than 50 ERCPs per year. Patients eligible for the study must be adults 18 years of age or older scheduled for ERCP. Patients with a history of a previous papillotomy and pregnant or breast-feeding women will be excluded from the study. Patients with severe pancreatobiliary disease, such as cholangiosepsis or severe pancreatitis, will be excluded from the study if they require an ERCP intervention from an experienced physician. The cannulation of the minor papilla is also an exclusion criterion, as it is often associated with additional challenges and risks. Patients who are unable to provide written informed consent or who are refusing participation in the study will also be excluded. If the supervising instructor is required to take over and perform the procedure himself, rather than allowing the participant to perform it supervised or telemedical assisted, the patient will be labelled as drop out.

Participant characteristics (PRO EDI)

In accordance with the PRO EDI reporting requirements for trial protocols (Trial Forge/PRO EDI initiative; <https://www.trialforge.org/trial-diversity/pro-edi/>), Table 1 summarises the six core demographic characteristics expected among trial participants and, where data will not be collected, provides the reasons for this.

Table 1. PRO EDI summary of expected demographic characteristics of trial participants

Characteristic	The people we would expect to see included
Age	Adults ≥18 years, no upper limit. ERCP indications (e.g. choledocholithiasis, biliary obstruction) become more common with age.
Sex	Both sexes eligible, except pregnancy/breast-feeding (procedural safety). No expected sex-based skew.
Gender	Gender identity is not recorded; only sex (as documented in medical records) is collected.
Race, ethnicity and ancestry	Not collected. Special category data under GDPR Art. 9, not routinely recorded in Germany.
Socio-economic status	Not collected, as it is not considered relevant to this trial's clinical procedure or eligibility.
Geographic location	Catchment area of Schwerin and rural Mecklenburg-Vorpommern; Helios Kliniken Schwerin is one of the larger ERCP centres serving this catchment area.

Who will take informed consent? {26a}

Informed consent from trial participants (patients) will be obtained by the investigator and authorized physicians before the study therapy.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable, no samples collected. Additional collection and use of participant data for other reasons as well as collection of biological specimens are not provided.

Interventions

Explanation for the choice of comparators {6b}

The choice of comparators was based on the need to evaluate the effectiveness of a specific training approach compared to standard training methods. Participants will be randomly assigned to one of two groups. The comparator group will receive standard face-to-face supervision during native papilla cannulation in ERCP. The experimental group will receive remote supervision via smart glasses. We aim to assess whether the new approach provides equivalent learning outcomes by comparing the performance of physicians in both groups. Key performance indicators, such as papilla cannulation time and adverse events during and after ERCP, will be used for evaluation. This comparison will be crucial for the determination of the potential benefits of telemedicine- based training using smart glasses.

Intervention description {11a}

In the intervention group, physicians will receive remote assistance during ERCP procedures via smart glasses. The smart glasses will provide a live video and audio connection to an experienced instructor. The instructor will guide the physician in real time. The instructor will provide verbal instructions and feedback as needed while observing the procedure through the video feed provided by the smart glasses. The primary outcome measure will begin once the physician has stabilised the endoscopic visualisation of the papilla in a stable position and will continue until the papilla is successfully cannulated using a guidewire or ERCP catheter. The instructor will be present in the neighbouring room and can physically assist or take over the examination at any time if necessary.

In the control group, physicians receive standard in-person assistance from an experienced instructor. The instructor will be present in the same room and will provide direct guidance and feedback throughout the entire procedure. Similar to the intervention group, the primary outcome measure will begin once the physician has stabilised the endoscopic visualisation of the papilla in a stable position and will continue until the papilla is successfully cannulated using a guidewire or ERCP catheter. Both interventions are designed to support the training of physicians in performing ERCP. They will be performed during scheduled clinical procedures. Instructors in both groups will have equivalent expertise in ERCP and teaching.

Criteria for discontinuing or modifying allocated interventions {11b}

Assigned interventions will be discontinued or modified under certain circumstances to ensure patient safety and the integrity of the study. If the supervising instructor determines that the patient's safety is at risk, the assigned intervention, whether remote assistance via smart glasses or in-person assistance, will be immediately terminated and the instructor will take over the procedure directly. In the intervention

group, technical issues such as loss of video or audio connection with the smart Glasses that cannot be resolved within a reasonable timeframe will result in termination of the intervention. In such cases, in-person assistance will be provided.

Additionally, the intervention will be stopped if the physician in training requests discontinuation due to discomfort, lack of confidence, or other personal reasons. In cases where the procedure duration exceeds the allocated time frame (e.g., 20 minutes) without successful papilla cannulation, or if the procedure becomes too complex for the participating physician, the instructor will intervene to ensure patient safety and procedural success. All instances of termination or modification of the procedure will be thoroughly documented, including the reasons for the decision and the actions taken.

Strategies to improve adherence to interventions {11c}

To improve compliance with the intervention protocols, all participating physicians will receive comprehensive training on the use of the smart glasses prior to the start of the study. This training will include practical demonstrations, detailed instructions, and a hands-on session to ensure familiarity with the smart glasses and the study workflow. For the intervention group, technical support will be available throughout the procedures from the principal investigator in a nearby room. This is to ensure that any potential problems with the smart glasses can be addressed in real time.

In both groups, protocol adherence will be monitored by the supervising instructors, who will observe the procedures and ensure that the intervention is being performed as intended. Any deviations from the protocol will be noted and documented in a dedicated case report form (CRF). These strategies are designed to maximize protocol fidelity and minimize variability in the implementation of the intervention.

Relevant concomitant care permitted or prohibited during the trial {11d}

During the trial, all physicians in training will have access to standard clinical care documents associated with ERCP, including pre-procedure preparations such as anticoagulation management and anything deemed necessary by the clinical team. Any additional technical or procedural assistance beyond the assigned intervention is strictly prohibited. Physicians in the smart glasses intervention group who received in-person assistance during the procedure will be excluded. Any additional care or interventions that deviate from the standard will be documented and reviewed by the study team to assess their potential impact on the study results. These measures are designed to minimize bias and ensure that any differences in outcomes are attributable to the assigned interventions.

Provisions for post-trial care {30}

Not applicable, as ancillary and post-trial care are not specifically planned for this study. All participants will receive standard post-procedural care following endoscopic retrograde cholangiopancreatography (ERCP) as per institutional guidelines, regardless of their involvement in the study. In addition, all patients will be observed for a follow-up period of 48 hours after ERCP, during which the study assistant will document in the CRF whether procedure related complications have occurred. Specifically, the

occurrence of cannulation-associated complications such as post-ERCP pancreatitis, cholangitis or other adverse events will be assessed.

Outcomes {12}

The primary outcome of the study is papilla cannulation time, defined as the time taken to successfully cannulate the native papilla during ERCP. The time from visualisation of the native papilla in a stable endoscope position to successful cannulation using a guide wire or ERCP catheter is measured. The time unit is seconds.

The secondary outcome is the occurrence of adverse events during and after the ERCP procedure. These events will be documented throughout the procedure and for the first 48 hours after ERCP.

Documentation of adverse events will include the occurrence of post-ERCP pancreatitis, defined as new or worsened abdominal pain persisting for more than 24 hours after ERCP, combined with an elevation of serum lipase greater than three times the upper limit of normal. Post-ERCP cholangitis is defined, in the context of this study, as a clearly new onset of cholangitis after ERCP or a pre-existing cholangitis that worsens because of the ERCP. Differential diagnosis must particularly consider biliary pancreatitis and other causes of cholangitis. In addition, any other complications or adverse events observed during or after the ERCP procedure will be recorded under the category "other". Furthermore, the following secondary variables will be assessed: the number of papilla contacts, the number of failed cannulations, whether a precut was performed (yes/no), and whether the supervising trainer had to take over the procedure (yes/no).

Participant timeline {13}

Patients will follow a structured timeline through the study, beginning with enrolment and informed consent. Patients will then be assigned to one of the two intervention groups (remote or in-person assistance) according to the study protocol. The intervention will be performed during the scheduled ERCP procedure.

Post-procedural assessments will be performed after ERCP to document adverse events. This information will be recorded using a form developed by our study team called the case report form.

The follow-up period will include monitoring for adverse events for up to 48 hours after the procedure. Overall study participation of the patients will typically last from enrolment through the 48-hour follow-up period, with all key data collected during this period.

Figure 1 presents the SPIRIT schedule of enrolment, interventions and assessments for this trial, summarising the timing of screening, informed consent, allocation, the two training interventions and outcome assessments relative to the ERCP procedure.

Sample size {14}

The `epi.sns.` function from the `epiR` R package was used to calculate the number of cases, taking the following parameters into account:

According to the literature, the mean value for successful cannulation of the native papilla by a doctor in training is 8.8 minutes (standard deviation $\pm$ 11.9 minutes).

A maximum extension of 5 minutes to the cannulation time is permitted for the experimental method to be considered non-inferior to the standard method. The statistical power should be at least 80%. The one-sided P value should be 0.05, as is usual for non-inferiority studies.

This results in a calculated number of cases of 75 per study arm. With a presumed dropout rate of 10% per arm, approximately 85 subjects are required per arm (= 170 in total).

Recruitment {15}

Participants will be recruited from patients scheduled for ERCP procedures at the Helios Kliniken Schwerin (Germany). As part of their routine care, eligible patients will be approached by the attending physician and invited to participate in the study. During the consultation, patients will receive detailed information about the study, including the purpose, procedures and potential risks. They will be given the opportunity to ask questions before making an informed decision. After informed consent, patients will be randomly assigned to one of the two intervention groups (smart glasses or in-person assistance) based on the study protocol.

Assignment of interventions: allocation

Sequence generation {16a}

For randomization, computer-generated random number sequences will be generated at the study centre in Schwerin. Odd numbers will represent the standard group (in-person assistance) and even numbers will represent the experimental group (remote assistance).

Sealed, sequentially numbered envelopes will be prepared by trained study personnel who are not involved in the study procedures or data collection. These envelopes will be opaque and securely sealed to prevent tampering. During the ERCP procedure, participants who meet the inclusion criteria will be randomised at a ratio of 1:1 by the treating endoscopist, who will open the envelope to reveal the assigned group.

The person responsible for preparing the envelopes will not be involved in patient care or study data collection, ensuring separation between sequence generation and intervention allocation. This process is designed to maintain the integrity of the randomization and prevent bias.

Concealment mechanism {16b}

The order of allocation will be concealed using sequentially numbered, opaque, sealed envelopes. Each envelope will contain the assigned intervention (smart glasses or in-person assistance) and will be prepared in advance by a study coordinator who is not involved in the recruitment process. At the time of enrolment, the responsible team member will open the next envelope in sequence to assign the patient to an intervention group. This ensures that allocation is concealed until the time of allocation and prevents any potential bias during the enrolment process.

Implementation {16c}

The allocation sequence is generated by the study coordinator using a computer-generated randomization process. The randomization sequence will be prepared in advance and stored securely to ensure the integrity of the random assignment process.

Participants will be enrolled by study team members who will inform eligible patients about the study and obtain informed consent. The enrolling staff will ensure that participants meet the inclusion criteria and are willing to participate in the study.

Once patients have provided informed consent, the study coordinator will assign them to one of the two intervention groups (smart glasses or in-person assistance) based on the generated allocation sequence. This process will be performed immediately prior to the ERCP procedure to ensure that the allocation is based solely on the randomization protocol and that no biases are introduced.

Assignment of interventions: Blinding

Who will be blinded {17a}

Since the interventions (smart glasses vs. in-person assistance) are visually distinct and immediately apparent to both the physician in training and the trainer, no blinding will be applied to the physicians. Physicians will be aware of which intervention they are receiving. In contrast, the participating patient will be blinded. This means that patients will not be informed about the type of intervention they will receive.

The physician in training will document the performed ERCP in a dedicated CRF and therefore will be aware of the intervention assignment. In contrast, data analysts will be blinded to the group assignments during the data analysis phase to prevent potential bias in the statistical evaluation.

Procedure for unblinding if needed {17b}

The participating patients will not be informed on the assignment and will not have access to the study documents showing which form of intervention (remote or in-person assisted) they have received.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Outcome data will be collected prospectively using a dedicated CRF for each participant, with trained study personnel responsible for data collection and documentation. Baseline data will include information such as age, gender and relevant medical history (e.g. previous ERCP procedures and comorbidities). This will be collected at the time of enrolment prior to the ERCP procedure.

The primary outcome is papilla cannulation time. This will be measured in seconds using a stopwatch from the moment the papilla is visualised in a stable endoscope position until successful cannulation is achieved by guidewire or ERCP catheter. This time will be recorded by the physician in training, and the entry is monitored by the trainer. Secondary outcomes include the occurrence of adverse events such as post-ERCP pancreatitis, cholangitis, papilla bleeding, perforation and other adverse events. These will be documented on the CRF after the procedure and monitored for up to 48 hours post-procedure.

The CRF is adapted from the Royal College of Physicians London ERCP DOPS form [4] and has been used in previous reviews [6], which confirmed its reliability and validity. The adapted version used in this study is included in Appendix 1, and the original version can be found via the source referenced.

To ensure data quality, all involved study personnel will be trained in proper documentation and use of the CRF. Paper forms will be stored and handled securely.

Plans to promote participant retention and complete follow-up {18b}

Each participating patient will be followed up to 24 hours after the intervention. Patients will be actively interviewed at the end of the hospital stay whether any adverse event has occurred after the intervention. If the patient has been discharged home before the 48-hour period has ended, a telephone call is made to the patient or their general practitioner to find out if any adverse events have occurred within the 48 hours following the intervention.

Data management {19}

Database set-up, double-entry data collection, data storage, and data validation are the responsibility of the principal investigator's study centre. All data management processes will be performed according to standard operating procedures (SOPs). Data validation includes checking the completeness, consistency and plausibility of the data documented in the CRF. For this purpose, a query system will be set up between data management and the investigator. In the so-called query process, requests for clarification of incomplete, implausible, and/or inconsistent data will be made as quickly as possible to the investigator by the data management team. These queries will be answered by the investigator, or a person appointed by the investigator and transmitted to the data management team for entry into the database. After all queries for all included patients have been clarified, the database will be closed at the end of the study and handed over to the biometrician for evaluation. After completion of all evaluations and preparation of the final report, the originals of all CRFs will be transferred to the PI for archiving. After completion of the study, the data will be converted into different data formats (e.g. csv files) to

ensure further use. The primary data on which the scientific publications are based will be publicly accessible for reanalyses and meta-analyses in the DRYAD repository (<https://datadryad.org>).after completion of the study.

Confidentiality {27}

Personal information about participants will be collected, stored and managed in with the highest standards of confidentiality. This includes safeguarding participants privacy and ensuring that all personal data are handled securely throughout the study. During the informed consent process, participants will be informed about the types of personal data collected. This includes all personal data such as contact information (name, address, phone number and email), demographic details, medical history and ERCP related outcomes. This information will be stored in a secure database, and access will be limited to authorized study personnel. To ensure privacy, all personal data will be pseudonymized, with each participant assigned unique study code. This code will be used for all study related data to ensure that participants identities remain confidential. The Data will be stored in locked cabinets, accessible only to authorized personnel.

The data will be stored, for the duration required by law. Once the analysis is completed, any personally identifiable data will no longer be necessary. Therefore, the file linking the participants to the study codes will be securely destroyed. The anonymized data will be kept in the study records, and the medical data must be stored for 30 years as required by law. During this time, the data will be kept in a secure way to prevent unauthorized access.

Only authorized study personnel will have access to the original data, and they are legally bound by confidentiality agreements. Any data shared for publication in scientific journals or conferences will be anonymized to ensure that participants identities are not disclosed.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable, no samples collected. Additional collection and use of participant data for other reasons as well as collection of biological specimens are not provided.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

An intention-to-treat analysis will be performed. Continuous variables, such as papilla cannulation time, will be reported as medians with their ranges (minimum and maximum), while categorical variables, such as the success rate of papilla cannulation and the occurrence of adverse events, will be reported as frequencies and percentages, unless otherwise stated.

For continuous variables, differences between treatment arms will be analysed using linear regression, potentially correcting for confounders such as physician experience, patient comorbidities, and other relevant factors. Categorical and binary outcomes will be analysed using logistic regression, also potentially adjusting for the above confounders.

Bonferroni correction will be applied to sub analyses of statistically significant tests, and corrected p-values < 0.05 will be considered significant.

The sample size was calculated using the `epi.ssninf` function from the R package *epiR*, assuming a mean cannulation time of 8.8 minutes in the control group (SD 11.9 minutes) with a non-inferiority margin of 5 minutes, a power of $\geq 80\%$, and a one-sided alpha of 0.05. A dropout rate of 10% per group is estimated, so approximately 85 participants per arm will be recruited.

Statistical analysis will be performed using R (version $\geq 3.3.0$). Subgroup analyses will be conducted separately for each trainee. A p-value < 0.05 will be considered statistically significant.

Interim analyses {21b}

A formal interim analysis is not planned. While in-person assistance is a standard and approved procedure, remote assistance via smart glasses is being evaluated in this study for its safety and effectiveness. Although serious safety-related events are not anticipated, the study includes thorough monitoring of adverse events to ensure patients' safety.

A Data Safety and Monitoring Committee (DSMC) will not be established. The steering committee will monitor recruitment progress and decide on any potential extension of the recruitment period if necessary, based on the recruitment figures.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Additional analyses will include subgroup analyses to evaluate potential differences in outcomes based on physician experience level (e.g., years of ERCP training) and patient characteristics (e.g., age, gender, or history of previous ERCP procedures) or ERCP techniques (e.g. precut papillotomy or pancreatic duct cannulation). These analyses will be performed to identify whether specific factors influence the primary outcome (papilla cannulation time) or secondary outcomes (adverse events). Subgroup analyses will be exploratory and will be performed with stratified statistical models. Results will be interpreted with caution due to potential sample size limitations in the subgroups.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

Not applicable, as protocol nonadherence and missing data are not expected as the intervention is performed by the physician, and the follow-up period is short (48 hours). However, if the follow-up

evaluation could not be completed, this will be considered in the final statistical analysis. There are no plans to implement statistical methods to calculate missing data.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The full study protocol is planned to be published in an international PubMed-registered journal (e.g. Trials). The anonymized participant-level data will be publicly accessible in the DRYAD repository (<https://datadryad.org>) after completion of the study.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

A steering committee (SC) will be set up, which will monitor the study together with the PI and decide on all issues or on issues to be defined, e.g. by majority vote. The composition of the steering committee is as follows: Chairperson Prof. Dr. Jörg-Peter Ritz (Head physician of Department of General and Visceral Surgery, Helios Kliniken Schwerin, Germany), Dr. med. Gaston Schley (Head of the study centre, Helios Kliniken Schwerin, Germany), and Herr Dr. med. Wolfgang Grüning (Head of Department of Pneumology, Helios Kliniken Schwerin, Germany). Other responsibilities within the scope of the study are listed below:

Project Management: Dr. med. Daniel Schmitz (PI), Helios Kliniken Schwerin, Germany

Data Management: Merve Güler (doctoral candidate), Helios Kliniken Schwerin, Germany

SAE Management: Prof. Dr. Jörg-Peter Ritz, Helios Kliniken Schwerin, Germany

Scientific Advice: Prof. Dr. Felix Grassmann, HMU Health and Medical University Potsdam, Germany

Composition of the data monitoring committee, its role and reporting structure {21a}

Not applicable. A Data Monitoring Committee (DMC) is not planned for this study. Due to the study's low risk and the nature of the intervention, the principal investigator will be responsible for monitoring the safety and progress of the study.

Adverse event reporting and harms {22}

In this study, all adverse events, both actively asked and spontaneously reported, will be documented and managed to ensure participants safety. These events will be recorded on the CRF. All severe adverse events will be reported to the PI and the trial steering committee within 24 hours. All events will be documented and stored in a secure database. Regular checks will ensure all adverse events are accurately reported.

Frequency and plans for auditing trial conduct {23}

The study will be regularly monitored through audits conducted by the trial steering committee to ensure the compliance with the study protocol and relevant regulations. The study lead will identify any

deviations from the protocol and implement corrective actions as needed.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any important amendments to the study protocol, including changes to eligibility criteria, outcomes, or analyses, will be communicated to all relevant parties. These changes will be formally documented and submitted to the relevant ethics committees for approval before being implemented.

Dissemination plans {31a}

Within one year of completing the clinical trial, a summary of the final report, including all significant events of the study, will be submitted to the responsible ethics committee. Following consultation with the sponsor (Helios Kliniken Schwerin), the PI, and all investigators of the study center, it is planned to present the results of the clinical trial in a PubMed-listed scientific journal and/or at German and international congresses. In principle, publication of the entire clinical trial is preferred. There are no restrictions on publication of the study results.

Discussion

The strength of the study design lies in its prospective, randomized approach, which focuses on a central, precisely measurable competence: the time taken to cannulate the native papilla during ERCP. Limitations in the evaluation could include an increased conversion rate from telemedical guidance to in-person guidance, or an uneven distribution of the difficulty level of ERCP procedures between the two randomized groups. All characteristics of the patient to be examined that influence the degree of difficulty are recorded in a standardized CRF (e.g. a juxtapapillary diverticulum). One potential difficulty might be the recruitment of patients. Since the study involves patients scheduled for ERCP procedures, their willingness to agree to participate in addition to their routine medical procedure is critical. To address this, we will ensure clear communication about the purpose and safety of the study. We will also ensure that the consent process is as simple and informed as possible. Another challenge may be the integration of telemedicine into the ERCP procedure. The use of smart glasses may lead to technical issues, such as connectivity or other problems that could disrupt the workflow. To address this, the study team will conduct regular equipment checks and provide technical support to ensure smooth operation. In addition, thorough training will be provided to physicians to minimize any difficulties in using this technology.

To avoid any complications with training on the smart glasses, the trainer will be located in the neighbouring room. If the trainee has difficulty implementing the verbal instructions, the trainer can take over the examination in a timely manner. These considerations are essential to ensure that the study is conducted effectively and that its objectives are achieved.

Trial status

This protocol represents version 3.0, dated 3 August 2026 and was basis of the ethical vote on 11 December 2024. Recruitment for the study began on 18.06.2025, and it is anticipated that the recruitment will be completed by 18.12.2026. Updates regarding the trials progress and any protocol modifications will be provided as necessary.

Abbreviations

CRF
case report form
DOPS
direct observation of procedural skills
ERCP
endoscopic retrograde cholangiopancreatography
PI
principal investigator
SOP
standard operating procedure

Declarations

Acknowledgements

Not applicable.

Authors' contributions {31b}

DS is the principal investigator; he designed the study and led the protocol development. MG contributed to the study design and protocol development and wrote the manuscript draft. MK contributed to the design of the study and provided comprehensive review of the manuscript. FG was the lead study methodologist and statistician. All authors read, revised the content of, and approved the final manuscript.

Funding {4}

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Availability of data and materials {29}

All study data will be made available on the DRYAD repository (<https://datadryad.org>). There are no contractual agreements restricting the investigators' access to the study data.

Ethics approval and consent to participate {24}

The study received ethics approval from 11 December 2024 (A2024-0212). Written informed consent will be obtained from all participants prior to their inclusion in the study.

Consent for publication {32}

All authors gave consent for publication of this study protocol.

Competing interests {28}

All authors declare that they have no competing interests.

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Figures

	STUDY PERIOD			
	Enrolment	Allocation	Post-allocation	Close-out
TIMEPOINT	-t1 (screening)	0 (randomisation)	t1 (ERCP procedure)	t2 (0-48 h follow-up)
ENROLMENT				
Eligibility screen (trainee physicians, ERCP trainers, patients)	X			
Informed consent (patients)	X			
Allocation (1:1 randomisation, sealed envelope)		X		
INTERVENTIONS				
Group 1: in-person instructor-led training			X	
Group 2: telemedical training via smart glasses			X	
ASSESSMENTS				
Baseline characteristics (age, sex, PRO EDI variables, medical history)	X			
Primary outcome: papilla cannulation time			X	
Secondary outcomes: papilla contacts, failed cannulations, precut performed, trainer take-over			X	
Adverse events (post-ERCP pancreatitis, cholangitis, other)			X	X

Figure 1

SPRIT schedule of enrolment, interventions and assessments

Supplementary Files

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- [5.ImageofsmartglassesEmeRaldStudy.docx](#)
- [6.Figureofsamplesizecalculation.pdf](#)
- [4.CRFVersion2.6.docx](#)
- [SPIRIT2025checklist.docx](#)