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NEURO-SUTURE: The influence of skin closure techniques on wound related complications in cranial oncological neurosurgical patients - interrupted transdermal vs running intradermal sutures: study protocol for a prospective, multicentre, interventional, open-label, randomized, parallel-group, non-inferiority trial.

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Study protocol

Keywords: Neurosurgery, intracranial tumor, wound healing, skin suturing, randomized controlled trial

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Title {1a}

NEURO-SUTURE: The influence of skin closure techniques on wound related complications in oncological neurosurgical patients - interrupted transdermal vs running intradermal sutures: study protocol for a prospective, multicentre, interventional, open-label, randomized, parallel-group, non-inferiority trial

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Abstract

Background: Postoperative wound healing is an important component of recovery in neurosurgical patients, especially in those undergoing surgery for intracranial tumors, where timely initiation of adjuvant therapy is essential. Despite the widespread use of different skin closure techniques, there is a lack of high-quality evidence comparing their effectiveness in cranial oncological neurosurgery. The choice of closure method is often based on surgeon preference rather than clinical data. This study aims to evaluate whether continuous intradermal absorbable sutures are non-inferior to conventional interrupted transdermal non-absorbable sutures in terms of wound healing outcomes.

Methods: This is a prospective, multicentre, randomized, open-label, parallel-group, non-inferiority trial conducted in three neurosurgical centres in Poland. A total of 382 adult patients undergoing elective craniotomy for supratentorial intracranial tumor will be enrolled and randomized in a 1:1 ratio to either continuous intradermal absorbable sutures or interrupted transdermal non-absorbable sutures for skin closure. The primary outcome is the occurrence of wound healing complications (including wound dehiscence, surgical site infection, or external cerebrospinal fluid leak) within 90 days postoperatively. Secondary outcomes include aesthetic assessment of wound healing, pain associated with suture removal, need for additional interventions, incidence of individual complications, and cost analysis. Outcome assessment will be partially blinded where feasible, supported by standardized training. Statistical analysis will follow a non-inferiority framework with a predefined margin of 5%.

Discussion: The trial addresses an important gap in neurosurgical practice by providing prospective randomized evidence on skin closure techniques in oncological patients. If continuous intradermal sutures are shown to be non-inferior, they may offer advantages such as improved cosmetic outcomes, elimination of suture removal, and increased patient comfort. The results may contribute to the development of standardized wound closure strategies and support incorporation of evidence-based practices into neurosurgical care pathways.

Trial registration: ClinicalTrials.gov NCT07413796. Registered on 4 February 2026.

Keywords

Neurosurgery; intracranial tumor; wound healing; skin suturing; randomized controlled trial

Structured summary {1b}

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT07413796
Date of registration in primary registry	4 February 2026
Secondary identifying numbers	KB/124/25
Source(s) of monetary material support	Medical University of Warsaw
Primary sponsor	Medical University of Warsaw
Secondary sponsor	N/A
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Contact for scientific queries	Michal Senger M.D +48 791 760 040 E-mail: michal.senger@wum.edu.pl
Public title	Skin closure techniques in oncological neurosurgery
Scientific title	The influence of skin closure techniques on wound related complications in oncological neurosurgery - interrupted

	transdermal vs running intradermal sutures. A prospective, multicentre, randomized, parallel-group, non-inferiority trial
Countries of recruitment	Poland
Health condition(s)	Surgery for an intracranial tumor
Intervention(s)	Intervention group: Skin closure using continuous intradermal absorbable suture Control group: Skin closure using interrupted transdermal non-absorbable sutures
Key inclusion and exclusion criteria	Inclusion criteria: • Adults ≥ 18 years old • Qualified for a craniotomy due to supratentorial intracranial tumor Exclusion criteria: • Revision surgery due to recurrent intracranial tumor • Emergency neurosurgical procedure • Scalp incision involving glabrous skin (e.g., forehead) or facial regions (e.g., eyebrow)
Study type	Interventional Allocation: randomised Intervention model: parallel assignment Primary outcome: efficacy
Date of first enrolment	5 February 2026
Target sample size	382
Recruitment status	Recruiting
Primary outcome(s)	Occurrence of surgical wound healing complication
Key secondary outcome(s)	1. Aesthetic quality of wound healing in patient and observer perspective

	2. Pain or discomfort related to sutures removal 3. Incidence and nature of additional interventions due to suboptimal wound healing 4. Incidence of external cerebrospinal fluid leak 5. Incidence of surgical site infections 6. Economic evaluation
Ethics review	Status: approved Approval date: 30.07.2025 Contact: Medical University of Warsaw Bioethics Committee
Data sharing statement	Data will be available to approved applicants after publication of the main findings within three years of the trial finishing. Clinical data access request to be sent to the Department of Neurosurgery and Pediatric Neurosurgery of Medical University of Warsaw (e-mail: neurochirurgia.csk@uckwum.pl).

Protocol version {2}

04.02.2026, Version 1.0

Introduction

Background and rationale {9a}

Postoperative wound healing is a critical aspect of recovery in surgical patients. In cranial neurosurgery, timely and uncomplicated wound healing is particularly crucial, especially among oncological patients. Surgery for an intracranial tumor is one of the most common cranial neurosurgical procedures, with secondary tumors and high-grade gliomas being the most prevalent histopathological diagnoses (1, 2) . In these cases, adjuvant therapy, including radiotherapy (RTH)

and/or chemotherapy (CTH), are integral parts of the standard treatment protocol (3-5), and is typically initiated within 4-6 weeks following surgery, during which a complete wound healing must occur (6-8). Any delay or complication in wound healing may postpone initiation or suspend adjuvant therapy, ultimately compromising survival outcomes (9).

Multiple factors influence the wound healing process, including cerebrospinal fluid (CSF) leakage, patient-related variables (e.g., comorbidities, nutritional status, smoking history) and the selection of surgical strategies (10-14). Evidence from other surgical specialties demonstrated that the choice of skin closure technique significantly affects postoperative wound healing outcomes (15-18). Methods commonly used for skin closure include interrupted transdermal non-absorbable sutures and continuous intradermal absorbable - each with distinct advantages and limitations. Although, these techniques have been assessed in various neurosurgical settings, evidence regarding their use in cranial oncological procedures remains extremely limited, and consequently the choice of skin closure often depends on individual surgeon preference and experience rather than high-quality reliable data (19-22).

Explanation for the choice of comparator {9b}

Findings from other surgical specialties and recommendations from Enhanced Recovery After Surgery (ERAS) guidelines suggest that continuous absorbable sutures may offer several advantages over conventional interrupted non-absorbable sutures. These include improved wound healing, reduced incidence of wound related complications, better cosmetic outcomes, greater patient comfort and enhanced overall quality of life (23-25). Given these potential benefits, it is reasonable to hypothesize that continuous suturing could be suitable for skin closure in neurosurgical oncological patients, in whom optimal wound healing is especially essential. The study protocol is developed in accordance with the SPIRIT 2025 statement (26).

Objectives {10}

The primary objective of this trial is to evaluate the incidence of complications related to postoperative wound healing following skin closure with continuous intradermal absorbable suture compared to conventional interrupted transdermal non-absorbable sutures in patients undergoing craniotomy for supratentorial intracranial tumor. Key secondary objectives include evaluation of aesthetics of postoperative wound healing in patient and investigator perspective, pain or discomfort related to sutures removal, incidence and nature of additional interventions due to suboptimal wound healing, incidence of surgical site infections and incidence of external cerebrospinal fluid leak.

The null hypothesis is that continuous intradermal sutures are inferior to interrupted transdermal sutures by more than the predefined non-inferiority margin of 5%. The alternative hypothesis is that continuous intradermal sutures are non-inferior to interrupted sutures, meaning that the difference in complication rates does not exceed the 5% margin.

Methods: Patient and public involvement, and trial design

Patient and public involvement {11}

Patients and the public were not involved in the design, conduct, reporting, or dissemination plans of this study.

Trial design {12}

This trial is designed as a prospective, multicentre, interventional, open-label, non-inferiority, randomized controlled trial with control group. The non-inferiority margin was set at an absolute difference of 5% in the incidence of wound healing complications, based on clinical judgment and considering the potential benefits of continuous intradermal sutures, including improved cosmetic outcomes, elimination of suture removal, and reduced procedure time. Participants will be randomly assigned in a 1:1 ratio to the intervention or control group. A total of 382 participants will be enrolled,

with 191 subjects assigned to the intervention (continuous absorbable suture) and 191 subjects assigned to the control group (interrupted non-absorbable sutures). Outcome assessment will be performed with partial blinding where feasible, as described in the assessment section.

Methods: Participants, interventions and outcomes

Trial setting {13}

Study recruitment will take place in Poland, in three participating neurosurgical departments: Department of Neurosurgery and Pediatric Neurosurgery, Medical University of Warsaw, Warsaw, Poland; Department of Neurosurgery and Oncology of Central Nervous System, Barlicki University Hospital, Medical University of Lodz, Lodz, Poland; Neurosurgery and Pediatric Neurosurgery Department in Lublin, Medical University of Lublin, Poland. Patients meeting the inclusion criteria will be invited to take part in the study by the research team members at each centre. Each patient qualified for an elective craniotomy due to supratentorial intracranial tumor will undergo screening. Each eligible participant will be assigned to one of the study groups according to the predefined randomization procedure. Both groups will be followed in the exact same manner. At the time of this protocol's preparation, the trial is planned as three centres study, however expansion to additional centres is possible.

Characteristics of the people who are needed for the trial

Characteristic	Description
Age	Adults ≥18 years
Sex	Male and female
Gender	Not specifically assessed

Race, ethnicity and ancestry	Predominantly European population
Socioeconomic status	Not specifically assessed
Geographic location	Poland
Other characteristics relevant to the trial	Patients qualified for first ever craniotomy due to any intracranial supratentorial tumor

Eligibility criteria for participants {14a}

Inclusion criteria

Participants must meet all the following criteria to be eligible for enrollment:

- Adults aged ≥ 18 years
- Qualified for a craniotomy due to supratentorial intracranial tumor

Exclusion criteria

Participants meeting any of the following criteria will be excluded from the study:

- Revision surgery due to recurrent brain tumor
- Emergency neurosurgical procedure
- Scalp incision involving glabrous skin (e.g., forehead) or facial regions (e.g., eyebrow)

Patients undergoing revision surgery are excluded due to the known impairment of wound healing associated under these conditions. Including such cases could compromise the assessment of skin healing quality, as the healing process in previously incised or metabolically compromised tissues differs substantially from that in healthy scalp tissue. Emergency neurosurgical procedures are also excluded, as incision patterns, intraoperative conditions, and overall management often deviate from those of planned elective craniotomies, potentially influencing wound healing outcomes. In cases where an incision involves glabrous skin or facial regions, wound closure will be performed

using a running intradermal suture due to the aesthetic importance of these areas, with conversion to transdermal sutures only if necessary. Future studies may address the effects of skin closure techniques in these specific patient subgroups. Except for those mentioned above, there are no relevant concomitant care or interventions that are prohibited during the trial.

Eligibility criteria for sites and those delivering interventions {14b}

All participating centres are neurosurgical units with experience in cranial tumor surgery and neurosurgical postoperative care.

Who will take informed consent? {32a}

Patients meeting the inclusion criteria and not meeting the exclusion criteria will be included in the trial after provision of the informed consent, which will be obtained by the research team members.

Additional consent provisions for collection and use of participant data and biological specimens {32b}

No additional consent for use of biological specimens is required, as no biological materials will be collected.

Intervention and comparator

Intervention and comparator description {15a}

The intervention consists of skin closure using a continuous intradermal absorbable suture placed within the dermis. The control group will include subjects with skin closed using interrupted transdermal non-absorbable sutures. Skin closure will be performed as the final step of the intracranial tumor resection by either the chief or assistant surgeon.

Criteria for discontinuing or modifying allocated intervention/comparator {15b}

Non-adherence to the assigned allocation may occur if, in the surgeon's judgment, patient safety could be compromised. Such circumstances may include unusual skin stiffness, tissue fragility or rupture that prevents completion of the closure with the assigned closing technique. Any deviation from the allocated method must be documented in the participant's dedicated randomization chart and justified accordingly. In such situations, interrupted transdermal non-absorbable sutures will be applied, as a standard, conventional closure technique. Regardless of the skin closure technique, closure of the remaining scalp layers will be performed in a standardized manner, independent of skin closure, and will include musculofascial layer closure and subcutaneous-pericranial layer closure, with the number of layers depending on incision localization.

Strategies to improve adherence to intervention/comparator {15c}

No specific strategies to improve adherence to the intervention protocols will be implemented due to the procedural nature of the trial and safety of the participants.

Concomitant care permitted or prohibited during the trial {15d}

There are no relevant concomitant care or interventions that are prohibited during the trial.

Ancillary and post-trial care {34}

All participants will receive ancillary care if required. Any adverse events or complications arising from trial participation will be promptly addressed and all necessary medical interventions will be provided.

Outcomes {16}

The primary outcome of this trial is the occurrence of surgical wound healing complication including wound dehiscence (defined as separation of wound edges longer than 1 cm), surgical site infection (SSI) or external cerebrospinal fluid leak within 90 days postoperatively.

Secondary outcomes:

1. Aesthetic quality of postoperative wound/scar evaluated using the Patient and Observer Scar Assessment Scale (POSAS) in investigator's perspective (from 9 to 45 points for the observer score) and patient's perspective (from 17 to 85 points for Patient score) where higher scores indicate worse healing outcomes.
2. Aesthetic quality of postoperative wound/scar using Visual Analogue Scale (VAS) (from 1 to 10 points) in investigator's and patient's perspective where higher score indicates better wound healing outcomes.
3. Pain or discomfort during sutures removal assessed using VAS (from 1 to 10 points) among subjects receiving non-absorbable sutures where higher score stands for the worst pain ever felt.
4. Incidence of additional invasive interventions due to suboptimal wound/scar formation. These interventions include placement of additional sutures within the wound (with assessment of amount of sutures placement and timing after primary surgical intervention), lumbar drainage placement (with assessment of timing of drainage placement after primary surgical intervention and duration of drainage placement), secondary surgical intervention (with assessment of timing secondary surgical intervention after primary surgical intervention).
5. Incidence of additional conservative management interventions due to suboptimal wound/scar formation. These interventions include antibiotic therapy and/or other forms of pharmacologic therapy with assessment of type of drugs used and therapy duration.
6. Incidence of cerebrospinal fluid leakage through the wound margins.

7. Incidence of surgical site infections (SSIs), based on clinical and/or radiologic evaluation categorized as superficial infections (skin erythema, swelling, tenderness, purulent/serous discharge) and deep infections (epidural/subdural empyema, abscess, skin necrosis)
8. Economic evaluation based on costs of materials used to perform skin closure in each group.

Harms {17}

The participants will be monitored for the adverse events potentially related to the skin closure techniques, which include SSI, wound dehiscence, unfavorable scarring, cerebrospinal fluid leak or allergic reactions to suturing material. These events are also captured as part of study outcomes and occurrence of any of these events will be recorded as a measure of inadequate wound healing. The case report form contains meticulous description of all potential adverse events. Although no other adverse events related to the study's intervention are anticipated, any unexpected complication will be promptly reported to the Bioethics Committee of the Medical University of Warsaw.

Participant timeline {18}

	TRIAL PERIOD					
	Enrollment and allocation	Post-allocation				Close-out
Time point	Day before the surgery	Day of the surgery	24 hours POD	7 days POD or during first outpatient clinic visit	90 days POD	Final assessment at 90 days POD
Eligibility screen Informed consent Allocation	X X X					
Interventions:						
Intervention group (continuous suture) Control group		X X				

(interrupted sutures)						
Assessments:						
Basic demographic data acquisition	X					
Wound length, closure time, scalp incision design		X				
Closure material and quantity used		X				
Pain/discomfort related to sutures removal				X		
Wound/scar healing quality			X	X	X	X

Sample size {19}

The analyses will be conducted following a non-inferiority trial framework. The non-inferiority margin was defined as an absolute difference of 5% in the incidence of wound healing complications. This margin was selected based on clinical relevance, assuming that a small increase in complication rates would be acceptable considering the potential benefits of continuous intradermal sutures. Expected prevalence of wound-healing complications in the control group is estimated at approximately 15% (a conservative estimate of 15% was used for sample size calculation based on available literature). Assuming a one-sided significance level of 0.025 and a statistical power of 80%, a total sample size of 382 participants (191 per group) is required to demonstrate non-inferiority.

Recruitment {20}

Participants will be recruited from neurosurgical departments of participating centres during routine clinical care.

Assignment of interventions: randomisation

Sequence generation: who will generate the sequence {21a}

Participants will be randomly assigned in a 1:1 ratio to either the intervention group (continuous intradermal absorbable sutures) or the control group (interrupted transdermal non-absorbable sutures). The randomization sequence will be generated using a computer-based random number generator with permuted blocks of varying sizes and stratified by study centre.

Sequence generation: type of randomisation {21b}

A block randomization scheme with variable block sizes (4 and 6) will be used to ensure a 1:1 allocation ratio between the intervention and control groups. To account for the multicentre design and to minimize potential centre-related bias, randomization will be stratified by study centre.

Allocation concealment mechanism {22}

Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes prepared centrally prior to study initiation. Each envelope will contain the group assignment according to the predefined randomization sequence. Envelopes will be identical in appearance and opened sequentially only after patient enrollment.

Implementation {23}

The randomization sequence will be generated by an independent statistician not involved in patient recruitment, treatment, or outcome assessment. Envelopes will be distributed to participating centres before study initiation. After confirming eligibility and obtaining informed consent, allocation will be revealed intraoperatively to the surgeon, prior to skin closure, by a member of the anesthesiology team.

Assignment of interventions: blinding

Who will be blinded {24a}

Due to the nature of the surgical intervention, blinding of the operating surgeon, operating room staff, and patients is not feasible.

How will be blinding be achieved {24b}

Although full blinding is not feasible due to the visible nature of the intervention, outcome assessment will be partially blinded where possible using independent assessors not involved in the surgical procedure to minimize assessment bias.

Procedure for unblinding if needed {24c}

N/A - due to the visible nature of the skin closure technique, full blinding of outcome assessors is not feasible.

Data collection and management

Plans for assessment and collection of outcomes {25a}

Prior to the surgery, demographic and clinical data including age, sex, height, weight, smoking history, preoperative hemoglobin levels and comorbidities will be collected from all participants. Each participant will be assigned a paper case report form (CRF) which will include detailed information and instructions regarding clinical assessment. In settings of the operating theatre the surgeon performing the skin closure will be asked to complete the following information:

- Name of the material and its quantity used to complete skin closure
- Quantity of closure material discarded e.g., due to thread rupture or loop/knot formation on the thread

- Length of the surgical wound, measured as the distance between the first suture entry point and the point of final thread cutting
- Time needed to complete the closure, defined as the period between first needle and cutting the thread once the skin edges are approximated
- Type of scalp incision pattern e.g., straight-line or flap incision

Postoperative wound and scar evaluations will be performed by a trained investigator using both physician-assessed and patient-reported POSAS and VAS scores at the following time points:

- 24 hours postoperatively
- First planned postoperative outpatient visit (typically 7–10 days post-surgery) or postoperative day 7 if hospitalization is prolonged
- 90-days postoperatively

To minimize observer variability and assessment bias, all investigators responsible for wound evaluation will undergo standardized training prior to study initiation. The training will include detailed instructions on the use of the POSAS and VAS, with emphasis on consistent interpretation of scoring criteria. Standardized digital photographs of the surgical wound will be obtained at predefined time points. In cases of uncertainty, wound photographs will be reviewed centrally by the principal investigator to reach a consensus assessment. Additionally, a subset of wound photographs will undergo central blinded review to ensure consistency and quality of outcome assessment across participating centres.

At the first postoperative visit (or postoperative day 7 for prolonged stays), patients will be additionally assessed for pain/discomfort during suture removal using the VAS. Pain/discomfort during suture removal will be assessed only in participants receiving non-absorbable sutures, as this procedure is not applicable to the absorbable suture group. Participants will receive standardized instructions to promptly report any signs of wound complications (e.g., redness, swelling, discharge, or dehiscence). All reported complications will be documented in the CRF, including detailed

information on the timing of onset within the postoperative period, the necessity for hospitalization, the type of treatment administered (e.g., pharmacotherapy, antibiotic therapy, or invasive interventions including surgical procedures), and the duration of the complication. The duration will be defined as the time interval from the onset of initial symptoms to complete clinical resolution. If no concerns are reported following scheduled assessments, the wound will be considered to have healed adequately. Each participant's observation period will extend from the date of surgery to 90 days postoperatively. In case of wound healing complication occurrence, subject's observation period could be extended beyond 90 days postoperatively till the moment of achieving satisfactory resolution of wound healing complications. The final aesthetic outcome will be evaluated at the end of the observation period and expressed as the mean value derived from all assessment time points.

Plans to promote participant retention and complete follow-up {25b}

Once enrolled and randomized, every effort will be made to follow subjects throughout the entire study duration. Participants may withdraw from the study for any reason at any time. In addition, participants may be withdrawn from the study by the investigators in cases of non-compliance with the study protocol, death, or loss to follow-up (i.e. inability to maintain contact with the participant despite reasonable efforts).

Data management {26}

Data will be recorded manually on paper CRFs and transferred to the main centre (Department of Neurosurgery and Pediatric Neurosurgery of the Medical University of Warsaw) for subsequent storage and evaluation. All collected data will be anonymized using unique study identification numbers. No personally identifiable information will be stored in the study database. All physical documents will be kept in a locked and access-restricted location. Study data will be retained for a minimum of three years following trial completion.

Confidentiality {33}

To preserve confidentiality and reduce the risk of identification during storage and analysis of data all personal information will be anonymized using unique study identifications numbers. All physical documents will be kept in a locked and access-restricted location.

Statistical methods

Statistical methods for primary and secondary outcomes {27a}

The primary outcome will be analyzed by comparing the proportion of patients with wound healing complications between groups. The primary outcome will be analyzed as a binary variable (presence or absence of wound healing complication). Categorical variables, including the primary outcome, will be compared using the chi-square test or Fisher's exact test, as appropriate. The absolute difference in complication rates between the intervention and control groups will be estimated along with a two-sided 95% confidence interval. Non-inferiority will be concluded if the upper bound of the confidence interval does not exceed the predefined non-inferiority margin of 5%. The primary analysis will be conducted on the per-protocol population, defined as participants who adhered to the assigned intervention and completed the required follow-up assessments. An intention-to-treat analysis, including all randomized participants regardless of protocol adherence, will be performed as a sensitivity analysis to assess the robustness of the results. Additionally, a multivariable logistic regression model will be used to adjust for potential confounders, including age, sex, smoking status, comorbidities, and study centre.

Who will be included in each analysis {27b}

The primary analysis will be conducted on the per-protocol population. The intention-to-treat population will include all randomized participants and will be used for sensitivity analysis.

How missing data will be handled in the analysis {27c}

In the event of missing data resulting from participant withdrawal, a multiple imputation approach will be applied. This method involves generating multiple complete datasets by imputing missing values based on observed data and its variability, followed by pooling the results to obtain overall estimates. Multiple imputation assumes that data are missing at random and appropriately accounts for the uncertainty associated with missing values. The primary analysis population will be defined based on protocol adherence, with compliance determined by the completion of at least the first or second and final evaluation time points. Participants meeting this minimum threshold will be included in the per-protocol. The intention-to-treat population will include all randomized participants, regardless of protocol adherence. Those who do not meet the minimum threshold criterion will be classified as non-compliant and considered protocol deviations and they will be analyzed separately to assess their potential impact on study outcomes.

Methods for additional analyses (e.g. subgroup analyses) {27d}

Additional analyses may include adjusted analyses using multivariable logistic regression models.

Interim analyses {28b}

A single interim analysis focused on safety will be performed once 50% of participants have completed the full observation period. The purpose of this analysis is to evaluate the occurrence and nature of adverse events. No criteria for early termination are planned, and the study is not designed to be stopped prematurely based on interim efficacy findings. Access to interim results will be limited to the study team, and the outcomes of this analysis will be reported to the principal investigator to support ongoing study oversight and decision-making.

Protocol and statistical analysis plan {5}

The full protocol, dataset and statistical plan are available at ClinicalTrials.gov, https://clinicaltrials.gov./study/NCT07413796

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {3d}

All roles and responsibilities, steering committee, endpoint adjudication and data management are overseen by the research team of the main centre, which is the Department of Neurosurgery and Pediatric Neurosurgery, Medical University of Warsaw.

Composition of the data monitoring committee, its role and reporting structure {28a}

Due to simple design, the independent data monitoring committee will not be formed. The research team will consistently review the results to ensure participants' safety and study integrity.

Frequency and plans for auditing trial conduct {29}

Auditing of trial conduct will be performed regularly to ensure protocol adherence, integrity of randomization process, data integrity, and participant safety. At each participating centre, monthly meetings will be held among members of the local research team to review study progress, assess compliance with the protocol, verify the consistency and quality of wound assessments, and address any emerging issues. The Trial Steering Committee will conduct formal audits every four months to provide independent oversight and confirm ongoing compliance with the study protocol. Any findings, concerns, or recommendations will be documented and reported to the principal investigator.

Protocol amendments {31}

Any important protocol modifications will be promptly reported to all relevant parties, including trial participants, bioethics committee, trial registries and the institutions associated with the research team. Documentation describing the nature of the modifications and their justification will be submitted to the bioethics committee. Updates will also be made to trial registries to maintain transparency. The research team will be informed of any changes during scheduled meetings to ensure their consistent understanding and implementation across study sites. Participants will be provided with written information outlining any changes that may influence their involvement, and additional informed consent will be obtained if required.

Dissemination policy {8}

The trial is registered in ClinicalTrials.gov. After data collection is complete, and within three years of completion, the results will be reported in ClinicalTrials.gov, including a flowchart of study recruitment and dropout, demographic and baseline characteristics of participants, primary and secondary outcomes, statistical test results, and adverse event information if applicable.

Discussion

The optimal technique for skin closure following neurosurgical procedures remains a topic of ongoing debate. Despite the widespread use of continuous intradermal sutures in various surgical disciplines and their inclusion in Enhanced Recovery After Surgery (ERAS) protocols there is a lack of high-quality evidence supporting their routine use in neurosurgical practice. Our study addresses this gap by directly comparing continuous intradermal sutures and interrupted skin sutures in patients undergoing craniotomy for supratentorial intracranial tumor.

Continuous sutures are often considered advantageous due to reduced suturing time and improved cosmetic results. Several studies in general, plastic, and obstetric surgery have supported these claims,

showing lower rates of wound dehiscence and higher patient satisfaction scores with continuous techniques (17). However, these findings cannot be directly extrapolated to neurosurgical patients, in whom specific anatomical and physiological factors - such as scalp tension, rich vascular supply, and proximity to hair-bearing skin may influence wound healing dynamics. In particular, the scalp is prone to hematoma formation and wound dehisence, which could theoretically compromise the reliability of continuous suture.

Previous studies evaluating closure techniques in neurosurgery have primarily focused on materials used, such as absorbable versus non-absorbable sutures, staples, tissue adhesives, or closure without shaving the incision line (21, 22, 27-32). Comparisons of actual suturing techniques are scarce, and none have comprehensively addressed postoperative complications or long-term cosmetic outcomes. Moreover, the presence of postoperative radiotherapy in many neuro-oncological patients further underscores the need for secure and complication-free wound healing. Delays in adjuvant treatment due to wound breakdown may significantly impact overall prognosis.

Importantly, this study may serve as a foundation for incorporating continuous intradermal sutures into neurosurgical ERAS protocols. If proven safe and effective, this closure technique could help enhance recovery by reducing closure time, minimizing postoperative complications, and improving long-term cosmetic outcomes - factors that are increasingly relevant in patient-centered surgical care. The inclusion of evidence-based wound closure methods in standardized perioperative pathways would represent a meaningful step toward optimizing outcomes in neuro-oncology.

Strengths of this study include its prospective randomized design, standardized assessment of both objective and subjective outcomes, multicentre settings and relevance to a common neurosurgical population. Major limitation is the fact that blinding of surgeons and patients to closure technique is challenging.

In conclusion, this trial seeks to generate evidence on the effectiveness and safety of continuous intradermal sutures in neurosurgical skin closure. Given the current lack of prospective data in this

specific field, the results have the potential to inform clinical guidelines and improve both surgical efficiency and patient-centered outcomes. Furthermore, they may contribute to the development of dedicated ERAS protocols in neurosurgery, incorporating continuous suturing as a standard approach to skin closure.

Trial status

Participants recruitment began in February 2026 and is expected to be completed by June 2027. Data collection is ongoing at the time of manuscript submission. The trial registry will be updated after completion of recruitment.

Abbreviations

RTH - radiotherapy; CTH - chemotherapy; CSF - cerebrospinal fluid; ERAS - Enhanced Recovery After Surgery; CRF - case report form; POSAS - Patient and Observer Scar Assessment Scale; VAS - Visual Analogue Scale; SSI - surgical site infection

Declarations

Acknowledgements

Not applicable

Authors' contributions {3a}

MS and TD conceived of the study and developed the protocol, presented the idea and supervised the project with input from KB and PK. MS and TD developed the statistical analysis plan. MS and KB wrote the first draft of the manuscript and subsequent versions, with critical feedback from TD and

PK. All authors have participated sufficiently in the conception and design of this work or the analysis and interpretation of the data, as well as the writing of the manuscript, to take public responsibility for it. The author(s) read and approved the final manuscript.

Sources of funding and other support {7a}

The funding is internal, by the Medical University of Warsaw

Availability of data and materials {6}

The principal investigator will oversee the intra-study data sharing process. All investigators at individual study sites will be given access to the cleaned data sets. Substantive contributions to the design, conduct, interpretation and reporting of the clinical trial will be recognized through the granting of authorship on the final trial report. The trial protocol, full study report, anonymized participant level dataset and statistical code for generating the results will be made publicly available if all investigators agree to share the data.

Ethics approval and consent to participate {30}

The Bioethics Committee of the Medical University of Warsaw approved the study protocol (KB/124/2025). An informed consent will be obtained from all study participants.

Consent for publication

Not applicable

Competing interests {7b}

The authors declare that they have no competing interests.

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