

A pragmatic randomized controlled trial of physician's-choice systemic anticancer therapy versus best supportive care in patients with end-stage advanced solid tumors: the TRUE trial protocol

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Study protocol

Keywords: End-stage advanced solid tumors, systemic anticancer therapy, best supportive care, pragmatic randomized controlled trial, quality of life

Posted Date: October 14th, 2026

DOI: <https://doi.org/10.21203/rs.3.rs-10169651/v1>

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Additional Declarations: No competing interests reported.

Abstract

Background

After guideline-recommended systemic anticancer therapy has been exhausted, additional systemic anticancer therapy is still sometimes administered in the end-stage setting, despite limited supporting evidence. Clinical guidelines caution that such treatment may worsen quality of life (QOL) without improving survival and may increase healthcare resource use and costs and discourage timely palliative care. However, some patients may still respond to the systemic therapy, leaving uncertainty about whether additional systemic anticancer therapy should be offered in this setting.

Methods

The TRUE trial is an ongoing multicenter, open-label, pragmatic randomized controlled trial designed to confirm the superiority of physician's-choice systemic anticancer therapy over best supportive care (BSC) in terms of overall survival (OS) in patients with end-stage advanced solid tumors. Secondary endpoints include QOL (EORTC QLQ-C30), EQ-5D-5L, quality-adjusted life years, and healthcare utilization through 12 weeks. A total of 300 patients will be enrolled from 46 institutions, with enrollment planned through 30 November 2027. The first participant was enrolled on 31 March 2025, and recruitment is ongoing.

Discussion

The TRUE trial is a pragmatic trial addressing how care should be prioritized for patients with advanced solid tumors who have exhausted guideline-recommended systemic options but remain eligible for further anticancer treatment. This is not a comparison of treatment versus no treatment; BSC represents active symptom-directed and supportive care, including palliative interventions when clinically indicated. By comparing physician's-choice systemic anticancer therapy with a time-limited BSC-prioritized strategy, and by assessing OS, QOL, health utility, quality-adjusted life years, and short-term healthcare utilization, the trial will clarify whether additional systemic therapy provides benefit that justifies its potential burdens, or whether prioritizing supportive and palliative care better supports patients' remaining time. The findings are expected to support shared decision-making in this ethically and clinically challenging setting.

Trial registration:

This trial was registered in the UMIN Clinical Trials Registry as UMIN000056086 on 7 November 2024. Recruitment is ongoing and had not been completed at the time of manuscript submission.

Background

Many patients with advanced solid tumors ultimately reach a point at which no further guideline-recommended systemic anticancer therapy can be actively recommended [1–3]. In routine practice, additional systemic anticancer therapy is sometimes administered in the end-stage setting despite limited supporting evidence, a phenomenon often referred to as “desperation oncology” [4].

Professional recommendations caution against low-value cancer-directed therapy in this context. The ‘Choosing Wisely “Top Five”’ list published by the American Society of Clinical Oncology advises against cancer-directed therapy for solid tumor patients with poor performance status (PS 3–4), who showed no benefit from prior evidence-based interventions, were ineligible for clinical trials, and for whom there is no strong evidence supporting further anticancer treatment, while noting two key exceptions: those with low PS due to other conditions and disease characteristics (e.g., mutations) suggesting a high likelihood of response [5]. Unlike conventional trials that evaluate the efficacy of a specific regimen, the TRUE trial examines the clinical value of systemic anticancer therapy at the point at which guideline-recommended standard options have been exhausted. Because it is a pragmatic randomized controlled trial, post-randomization care is intended to closely reflect routine practice [6, 7]. Importantly, the trial will provide patient-centered evidence, including quality of life (QOL) and health-economic outcomes, to inform decisions about how patients may best use their limited time in the end-stage setting [8–11].

We therefore designed the TRUE trial as a pragmatic, multicenter, open-label, phase III randomized controlled trial to confirm the superiority of physician’s-choice systemic anticancer therapy over best supportive care (BSC) in terms of overall survival (OS) in patients with end-stage advanced solid tumors. Indefinite assignment to BSC may be difficult for patient consent and may unduly restrict care options in an era of rapidly evolving therapies. Therefore, the protocol prespecifies a 12-week BSC-only strategy period in the control arm after registration, followed by flexible management at the treating physician’s discretion. This design aims to preserve real-world flexibility while maintaining the rigor of randomization, and to address a clinically critical question for patients who may experience a relatively stable interval early after enrollment.

The study protocol was reviewed and approved by the Aichi Cancer Center Hospital Institutional Review Board, which serves as the central IRB for this multicenter study (approval number: IR061112). This trial was registered in the UMIN Clinical Trials Registry as UMIN000056086 on 7 November 2024 [12]. The first participant was enrolled on 31 March 2025, and recruitment is ongoing.

Methods/Design

Objectives

The aim of this study is to confirm the superiority of physician’s-choice systemic anticancer therapy over BSC in terms of OS in patients with end-stage advanced solid tumors.

Study design

This study is a multi-institutional, two-arm, open-label, randomized phase III trial. The study design is depicted in Fig. 1. The planned enrollment period is from the date of institutional approval through 30 November 2027, and participants will be followed for vital status through 30 November 2029, corresponding to up to 2 years after completion of enrollment.

The current manuscript is based on protocol version 1.1, dated 1 September 2025, which was approved by the Aichi Cancer Center Hospital Institutional Review Board on 16 September 2025. Protocol amendments will be initiated and reviewed by the trial steering/executive committee. Substantive amendments will be implemented only after prior agreement by the principal investigator and approval through the Research Ethics Committee/Institutional Review Board process, including the Aichi Cancer Center Hospital Institutional Review Board and relevant institutional approvals, as applicable. In urgent situations requiring immediate protocol deviations or changes to avoid hazards to participants, such deviations or changes may be undertaken prior to formal approval; however, the rationale and details will be promptly documented and submitted. The amendment will subsequently be approved by the principal investigator, the Aichi Cancer Center Hospital Institutional Review Board, and the head of the participating institution, as applicable. Substantive amendments will also be communicated to relevant parties, including participating sites and the trial registry, as required.

Patient and public involvement

Patients and members of the public were not directly involved in the initial design of this trial. However, the protocol was designed to address patient-centered decision-making in the end-stage setting by incorporating health-related quality of life (HRQOL), health utility, quality-adjusted life years (QALYs), and healthcare utilization as secondary outcomes. The investigators plan to consider patient and public perspectives in the interpretation and dissemination of the trial findings, including the preparation of accessible summaries where feasible.

Endpoints

The primary endpoint is OS in all randomized patients. OS is defined as the time (days) from the date of randomization to death by any cause. Patients without a documented death at the time of analysis will be censored at the date last known to be alive.

The secondary endpoints are HRQOL assessed by the EORTC QLQ-C30 [13], health utility assessed by the EQ-5D-5L [14], medical economic outcomes including QALYs, total length of hospitalization (days) through 12 weeks after randomization, number of unscheduled outpatient visit days through 12 weeks after randomization, and number of emergency department visits and other unscheduled outpatient visits through 12 weeks after randomization.

Eligibility criteria

Inclusion criteria at registration

For inclusion in the registration, patients are required to fulfill all the following criteria: 1) Histologically or cytologically confirmed advanced solid tumor, including breast, lung, gastric, colorectal, hepatobiliary–pancreatic, gynecologic, or urologic cancers; 2) Advanced, metastatic, or recurrent cancer that is not amenable to curative resection or definitive radiotherapy; 3) Further guideline-recommended systemic anticancer therapy is not strongly recommended by the attending physician; 4) Non–guideline-recommended systemic anticancer therapies may still be in use in routine practice; 5) Not scheduled to undergo gene panel testing; 6) Aged 18 years or over at enrollment; 7) PS is 0, 1, or 2 according to ECOG criteria; 8) Measurable disease is not required; 9) No symptomatic brain metastases and no spinal metastases requiring radiation or surgical procedures; 10) Able to make outpatient visits; 11) Organ function sufficiently preserved to receive drug therapies; 12) Able to complete QOL surveys using an electronic device; 13) Patient’s written consent to participate in the study has been obtained.

Exclusion criteria

Patients are excluded from the registration pre-operatively if they meet any of the following criteria: 1) Infectious diseases requiring physical treatment; 2) Psychiatric disorders/symptoms that interfere with daily life and make it difficult to participate in the study; 3) Pregnant, possibly pregnant, within 28 days postpartum, or breastfeeding; 4) Participation in the study judged to be not feasible by the attending physician.

Randomization

Registration is conducted through a centralized, web-based system. Eligible patients are randomized in a 1:1 ratio to receive either BSC (control arm) or physician’s-choice systemic anticancer therapy (experimental arm). Randomization is performed using the minimization method with a random component, balanced with PS (0–1 vs 2), age (≤ 74 vs ≥ 75 years), and tumor type (favorable-prognosis cancers [prostate and breast] vs others).

The allocation procedure is implemented and managed within the centralized web-based system; personnel responsible for enrollment and assignment will not have access to the random allocation sequence in advance, and treatment assignment is revealed only after registration data are entered and confirmed.

This is an open-label trial; therefore, participants, treating clinicians, and study personnel will not be blinded after assignment. Data analysts will be blinded to group allocation where feasible (e.g., using masked group labels such as A/B) until database lock and/or finalization of the statistical analysis plan, as applicable.

Treatments

Patients are randomized to BSC or a physician's-choice systemic anticancer therapy strategy.

In the control arm, patients receive BSC. BSC includes pain control, including opioids and invasive procedures such as nerve blocks; oxygen therapy for dyspnea; appropriate fluid therapy and correction of electrolyte abnormalities; palliative radiotherapy; stenting or bypass procedures for obstruction; aspiration or drainage, with pleurodesis when indicated; treatment of infections and thrombosis; pharmacologic treatment for symptoms such as nausea, anorexia, and malaise; psycho-oncological support and treatment for depression, insomnia, and anxiety; and other non-invasive measures considered useful for maintaining QOL and relieving symptoms. In principle, mechanical ventilation, circulatory support, hemodialysis, total parenteral nutrition, and enteral nutrition via tube or fistula are not included in BSC. Systemic anticancer therapy is not administered through 12 weeks after registration. From week 13 onward, systemic anticancer therapy may be initiated at the discretion of the treating physician.

In the experimental arm, physician's-choice systemic anticancer therapy is initiated within 14 days after enrollment. The specific regimen is not mandated by the protocol. The treating physician selects the treatment, provided that the drug, dose, and administration are approved under the Japanese health insurance system for the relevant malignancy. No protocol-specific treatment-modification criteria are stipulated. All administered systemic anticancer therapies and relevant details (e.g., agent, dose, schedule, start/stop dates, and modifications) are recorded in an electronic data capture system. Supportive care and symptom-directed local interventions are allowed throughout, as clinically indicated.

In both arms, subsequent management is not restricted by the protocol after the initial strategy period.

Follow-up

All randomized patients will be followed for vital status. Because this is a pragmatic randomized controlled trial, post-randomization management is largely observational and conducted according to routine practice, with no protocol-mandated treatment regimens or schedules of assessments.

Safety data collection is limited to serious adverse events (SAEs) occurring within 12 weeks after registration. SAEs attributable to progression of the underlying cancer are not collected. For effectiveness, only vital status, date of death, and cause of death are assessed.

Patient-reported outcomes are collected using electronic patient-reported outcomes questionnaires. EORTC QLQ-C30 and EQ-5D-5L are completed at registration (allowed window: within 1 week) and at weeks 4, 8, 12, 16, 20, and 24 after registration (allowed window: ± 1 week). Thereafter, EQ-5D-5L is collected every 8 weeks (allowed window: ± 1 week) until the end of follow-up. These endpoints were selected to capture patient-centered outcomes relevant to decision-making in the end-stage setting, including how patients may best use their remaining time.

Statistical analysis

This phase III randomized trial is designed to confirm the superiority of physician's-choice systemic anticancer therapy over BSC in terms of OS. The primary hypothesis is that OS in the physician's-choice arm is longer than that in the BSC arm. If superiority is demonstrated, physician's-choice systemic anticancer therapy will be considered a more useful strategy; if not, BSC will remain the standard approach in this setting.

The number and proportion of enrolled patients will be summarized by cancer type to describe differences in recruitment across cancer types. The primary analysis will be conducted in the full analysis set, which includes all enrolled patients who initiated the allocated treatment. OS will be summarized using the Kaplan–Meier method. The null hypothesis that the two survival curves are identical will be tested using a log-rank test stratified by the allocation factors (PS [0–1 vs 2], age [≤ 74 vs ≥ 75 years], and tumor type [favorable-prognosis cancers (prostate, breast) vs others]). In addition, a stratified Cox proportional hazards model will be fitted to estimate the hazard ratio (physician's-choice vs BSC) with a two-sided 95% confidence interval. Statistical significance will be assessed at a two-sided $\alpha = 0.05$. Prespecified subgroup analyses will be conducted according to these allocation factors, to explore the consistency of the treatment effect across clinically relevant subgroups. Thus, differences in prognosis related to tumor type are accounted for in the primary analysis, while potential differences in treatment effect are explored in the prespecified subgroup analysis by tumor type. For sample size determination, the median OS in the BSC arm is assumed to be 6 months, based on cancer-specific prognosis estimates weighted according to the distribution of cancer deaths in Japan, and a clinically meaningful improvement is defined as a 3-month prolongation; thus, the expected median OS in the physician's-choice arm is 9 months. This 3-month improvement was considered clinically meaningful in this end-stage setting, because it represents a substantial relative survival gain while requiring interpretation together with QOL, treatment burden, and healthcare utilization, consistent with value-based frameworks such as the ESMO Magnitude of Clinical Benefit Scale. Assuming exponential survival distribution, two-sided $\alpha = 0.05$, 90% power, an accrual period of 3 years with uniform enrollment, and a follow-up period of 2 years, 272 patients (required events: 263) are needed. Allowing for approximately 10% dropout and a planned interim analysis for efficacy, the target sample size is set at 300 patients (150 per arm). All statistical analyses will be performed under the control of the trial statistician (TK).

For OS, vital status and survival dates will be queried and resolved where possible before database lock. For patient-reported outcomes, including EORTC QLQ-C30 and EQ-5D-5L, analyses will primarily use all available data collected at each scheduled assessment time point. The extent and patterns of missing data will be summarized by treatment group and assessment time point. Where appropriate, sensitivity analyses using multiple imputation or mixed-effects models under plausible missing data assumptions will be performed to assess the robustness of the findings. Participants who discontinue the allocated strategy or deviate from the protocol will continue to be followed for vital status and patient-reported outcomes whenever possible.

Interim analysis and monitoring

In addition to blinded monitoring, one interim analysis with between-group comparison will be performed when approximately 130 deaths have been observed. An O'Brien–Fleming-type stopping boundary will be applied. If the between-group comparison for the primary endpoint meets the stopping criterion (two-sided $p < 0.0031$), the primary objective will be considered achieved, and an independent data monitoring committee (DMC) will recommend early termination of the trial to the study chair. The final analysis will be conducted using a two-sided significance level of $p = 0.049$. If the trial is stopped early, the results will be promptly disseminated at scientific meetings and published in a peer-reviewed journal.

The independent DMC comprises three members with expertise in clinical oncology and biostatistics, none of whom are involved in the conduct of the trial. The DMC reviews accumulating trial data (including safety data and the interim efficacy analysis) and provides recommendations regarding trial continuation, modification, or early termination. The DMC reports its recommendations to the study chair. The DMC is independent of the sponsor and funder, and all members disclose and manage potential conflicts of interest. Further details are described in the DMC charter, which is available from the coordinating center upon request.

De-identified individual participant data, the data dictionary, and statistical code used to generate the primary results will be made available to trial investigators and qualified external researchers on reasonable request after publication of the primary results, subject to applicable ethics approvals and data protection requirements. Requests will be reviewed by the study chair (and/or steering committee, as applicable), and data will be shared via secure, encrypted transfer under a data use agreement. No additional intervention materials requiring separate dissemination are planned.

Participating institutions (from North to South)

Kushiro Rosai Hospital, Sapporo Medical University Hospital, Teine Keijinkai Hospital, Sapporo City General Hospital, Iwate Medical University, Akita University Hospital, Nihonkai General Hospital, University of Tsukuba Hospital, Jichi Medical University Hospital, Tochigi Cancer Center, Gunma Prefectural Cancer Center, Showa Medical University Koto Toyosu Hospital, Japanese Red Cross Medical Center, Keio University Hospital, Tokyo Metropolitan Police Hospital, Toho University Omori Medical Center, Kyorin University Hospital, St. Marianna University Hospital, International Goodwill Hospital, University of Toyama, Faculty of Medicine, University of Fukui Hospital, University of Yamanashi, Faculty of Medicine, International University of Health and Welfare Atami Hospital, Seirei Hamamatsu General Hospital, Gifu University Hospital, Toyohashi Municipal Hospital, Aichi Cancer Center, Toyota Memorial Hospital, Nagoya University Hospital, Osaka Medical and Pharmaceutical University Hospital, Osaka International Cancer Institute, Hyogo Medical University, Kansai Rosai Hospital, Hyogo Prefectural Amagasaki General Medical Center, Okayama University Hospital, Okayama Medical Center, Kawasaki Medical School Hospital, Hiroshima University Hospital, Yamaguchi University Hospital, Shikoku Cancer Center, Kochi Medical School, Kyushu Medical Center, Japanese Red Cross Nagasaki Genbaku Hospital, Oita University Hospital, Kagoshima University Hospital, and Okinawa Hospital.

Dissemination policy

The trial results will be disseminated through reporting in the trial registry, presentation at scientific meetings, and publication in a peer-reviewed open access journal. Conference abstracts and manuscripts will be prepared by the study investigators and approved by the principal investigator and the trial steering/executive committee before submission. Authorship of trial-related publications will be determined according to the International Committee of Medical Journal Editors authorship criteria and the contributions of individual investigators.

Discussion

The TRUE trial is designed to address a difficult and common question in routine oncology practice: how care should be prioritized for patients with end-stage advanced solid tumors who have exhausted guideline-recommended systemic anticancer therapy but remain eligible for further treatment. In this setting, additional systemic anticancer therapy is sometimes continued or initiated despite limited evidence, while clinicians, patients, and families must also consider symptom burden, QOL, the feasibility of palliative procedures, healthcare utilization, and the patient's remaining time. The TRUE trial therefore evaluates not a single mandated regimen, but a pragmatic treatment strategy: prioritizing physician's-choice systemic anticancer therapy versus prioritizing BSC and symptom-directed supportive or palliative interventions.

An important point is that this trial is not a comparison of treatment versus no treatment. BSC in this protocol represents active, specialized, symptom-directed care. It may include pharmacologic palliation, psychosocial support, palliative radiotherapy, drainage procedures, bypass surgery, and other supportive or palliative interventions when clinically indicated. These interventions are often central to the care of patients with end-stage advanced cancer. In some circumstances, systemic anticancer therapy may delay, complicate, or limit the feasibility of such interventions because of treatment-related toxicities, myelosuppression, deterioration in general condition, or the need to prioritize time and clinical resources. Thus, the key clinical question addressed by the TRUE trial is whether, during a clinically meaningful early period, patients are better served by prioritizing additional systemic anticancer therapy or by prioritizing BSC and palliative/supportive care.

A distinctive feature of this protocol is the prespecified 12-week period in the control arm during which systemic anticancer therapy is withheld, while BSC and symptom-directed interventions are provided as clinically indicated. This time-limited strategy window was chosen to make randomization ethically and practically feasible while preserving a meaningful comparison between care-prioritization strategies. From week 13 onward, subsequent management is left to the discretion of the treating physician. This design reflects the realities of contemporary oncology practice, in which treatment options may evolve, patients' conditions may change rapidly, and rigid long-term restriction of treatment may be unacceptable to patients and clinicians.

The pragmatic nature of the TRUE trial is central to its design. The protocol deliberately does not mandate a specific systemic anticancer regimen, nor does it impose intensive trial-specific assessment schedules beyond those needed to collect key outcomes. Instead, care after randomization is intended to remain close to routine practice, allowing treating physicians to manage individual symptoms and complications according to each patient's clinical situation. This approach may introduce treatment heterogeneity and may dilute between-group differences, particularly because crossover to systemic therapy is permitted after week 13 in the control strategy and may attenuate differences in OS between the groups. However, these features are not merely limitations; they are essential to evaluating the effectiveness of real-world clinical strategies rather than the efficacy of a single drug regimen under highly controlled conditions.

Although OS is the primary endpoint, survival alone is insufficient to determine the value of additional systemic therapy in this setting. For patients approaching the end of life, the relevant trade-off includes potential survival benefit, QOL, health utility, QALYs, treatment burden, hospitalization, unscheduled outpatient visits, emergency visits, and opportunities to receive timely symptom-directed interventions. Therefore, the TRUE trial incorporates patient-reported outcomes and health-economic measures, including HRQOL assessed in accordance with the EORTC QLQ-C30, health utility assessed in accordance with the EQ-5D-5L, QALYs, and short-term healthcare utilization through 12 weeks. This outcome set is intended to clarify whether additional systemic therapy provides benefit that justifies its potential burdens, or whether a BSC-prioritized strategy better supports patients' remaining time.

Several design features should be considered when interpreting the future results. The physician's-choice arm will include heterogeneous systemic therapies, reflecting the diversity of tumor types, prior treatments, physician judgment, and patient preferences encountered in routine practice. Safety data collection is intentionally limited to SAEs within 12 weeks, and SAEs attributable to progression of the underlying cancer are not collected. These features support the feasibility and pragmatic nature of the trial, although they may limit detailed comparisons of toxicity profiles and attribution of adverse events.

The trial is powered to detect a clinically meaningful improvement in OS, assuming a median OS of 6 months in the BSC arm and 9 months in the physician's-choice therapy arm, with a target sample size of 300 patients and a planned interim analysis after approximately 130 deaths using an O'Brien–Fleming-type boundary. Whether the trial demonstrates superiority of physician's-choice systemic therapy or supports a BSC-prioritized approach, the results are expected to provide evidence for discussing treatment priorities with patients after guideline-recommended options have been exhausted.

Abbreviations

BSC

best supportive care

DMC

data monitoring committee

HRQOL

health-related quality of life

OS

overall survival

PS

performance status

QALY

quality-adjusted life year

QOL

quality of life

SAE

serious adverse event

TRUE

Therapy for Patients with Advanced Solid Tumors in the End-stage

Declarations

Ethics approval and consent to participate

The study protocol was reviewed and approved by the Aichi Cancer Center Hospital Institutional Review Board, which serves as the central IRB for this multicenter study (approval number: IR061112). Following central IRB approval, each participating institution obtains the required institutional authorization before study initiation. Written informed consent is obtained from all participants by a subinvestigator before their participation in any trial-specific procedures, after providing an explanation of the study and allowing sufficient time for questions. To protect confidentiality, personal information of potential and enrolled participants is collected only as necessary for trial conduct; participants are assigned a unique study identification number, and identifiable information is stored separately from study data with access restricted to authorized study personnel. Study data are entered and managed in the electronic data capture system using the study identification number, and any sharing with monitors/auditors or regulatory and ethics oversight bodies is limited to the minimum necessary under confidentiality safeguards.

No datasets have been generated or analyzed for the current protocol manuscript. De-identified individual participant data generated during the trial, the data dictionary, and statistical code used to generate the primary results will be made available to qualified researchers on reasonable requests after publication of the primary results, subject to applicable ethics approvals, data protection requirements, and a data use agreement.

Consent for publication

Not applicable. No individually identifiable participant data (including individual details, images, or videos) will be published in this study. All data presented will be anonymized/aggregated to prevent identification of individual participants.

Availability of data and materials

Data sharing is not applicable, as no datasets were generated or analyzed for the current protocol manuscript. De-identified participant data generated during the trial will be available from the corresponding author on reasonable requests after publication of the primary results, subject to applicable ethics approvals, data protection requirements, and a data use agreement.

Competing interests

All authors state that they have no conflicts of interest associated with this manuscript.

Funding

This study is sponsored by the National Institute of Public Health (NIPH), Japan. Sponsor contact information is as follows: Takeru Shirowa, Center for Outcomes Research and Economic Evaluation for Health CORE2 Health, National Institute of Public Health, 2-3-6 Minami, Wako City, Saitama Prefecture, Japan; Email: t.shirowa@icer.jp. The study is conducted under an agreement between NIPH and the Public Health Research Foundation (PHRF). PHRF contact information is as follows: Comprehensive Support Project for Oncology Research (CSPOR)/Atsuko Nakasato, Public Health Research Foundation, 1-1-7 Nishi-waseda, Shinjuku, Tokyo 169-0051, Japan; Email: csp-qol@csp.or.jp. PHRF serves as the administrative office and pays study-related funds required at participating institutions.

PHRF is also responsible for handling inquiries related to fund management.

The trial is designed and conducted by the study investigators under the oversight of the principal investigator and the trial steering/executive committee. Statistical analysis, interpretation of the results, and preparation of manuscripts will be performed by the study investigators. The sponsor and funder will not have authority to suppress publication of any of the trial results.

Authors' contributions

TM and HK contributed to the conception and design of the study. TM, TI, TKa, MU, SK, TKu, AT, RT, KH, YM, HK, and KM contributed to data collection. TM, TI, TKa, HK, and KM contributed to analysis and interpretation. HK was responsible for project administration. All authors critically reviewed the manuscript and read and approved the final manuscript.

Acknowledgements

We are grateful to all enrolled patients and investigators for their cooperation in the TRUE trial.

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Figures

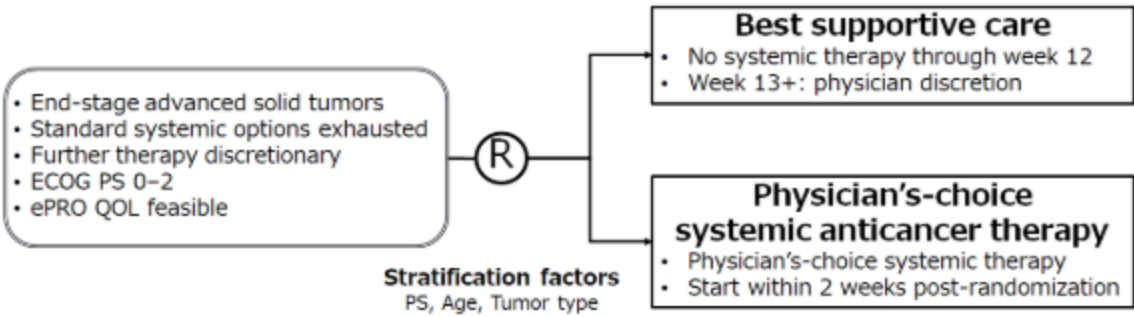


Figure 1

Design of the TRUE trial

ECOG, Eastern Cooperative Oncology Group; ePRO, electronic patient-reported outcome; PS, performance status; QOL, quality of life; R, randomization

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

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