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Can we save the rectum by watchful waiting or transanal surgery following (chemo) radiotherapy versus total mesorectal excision for early rectal cancer?

Submission date
26/09/2016

Recruitment status
No longer recruiting

Registration date
20/10/2016

Overall study status
Ongoing

Last Edited
14/11/2022

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-surgery-or-different-types-of-radiotherapy-for-rectal-cancer-star-trec

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2016-000862-49

ClinicalTrials.gov (NCT)
NCT02945566

Protocol serial number
CPMS 31203

Study information

Scientific Title
STAR-TREC: Can we Save the rectum by watchful waiting or TransAnal surgery following (chemo) Radiotherapy versus Total mesorectal excision for early REctal Cancer?

Acronym
STAR-TReC

Study objectives
Current study hypothesis as of 28/06/2021:
The phase II component will assess the feasibility of a large, multi-centre randomised trial comparing radical surgery versus organ saving treatment using (chemo)radiotherapy followed by selective transanal microsurgery.
The phase III component will evaluate two contrasting organ preservation strategies (either long-course chemoradiotherapy or short-course radiotherapy) for the treatment of early stage rectal cancer in terms of organ preservation rates, toxicity (clinician and patient-reported) and Health-Related Quality of Life (HRQoL).
The phase III study will also include a standard TME radical surgery (non- randomised) comparator arm encompassing reconstructive (low anterior resection) and non-reconstructive (abdominoperineal excision, low Hartmann's procedure) approaches.

Previous study hypothesis:
The aim of this study is to assess the feasibility of successfully recruiting to a large, multi-centre randomised trial comparing radical surgery versus organ saving treatment using (chemo) radiotherapy followed by selective transanal microsurgery, to evaluate whether it is possible to accelerate patient recruitment from 2 per month, as attained in the previous TREC study, to 6 per month over a two-year period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands – Leicester Central Research Ethics Committee, 23/09/2016, 16/EM/0186

Study design
An international multi-centre randomized phase II feasibility trial and an international multi-centre open-label rolling phase II/III trial with a partially randomised patient preference design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cancer, Primary sub-specialty: Colorectal; UKCRC code/ Disease: Cancer/ Malignant neoplasms of digestive organs

Interventions
Current interventions as of 28/06/2021:
Patients will be recruited following informed consent, which will be conducted in accordance with Good Clinical Practice standards, after all baseline assessments are completed and all eligibility criteria have been confirmed. STAR-TREC is a rolling phase II/III study comprising the following components:

Phase II:
The STAR-TREC phase II feasibility component is an international, multi-centre, randomised trial, comprising a 1:1:1 randomisation for eligible subjects with a small, clinically localised rectal cancer between:
1. Conventional TME surgery
2. Organ saving utilising long course concurrent chemoradiation
3. Organ saving utilising short course preoperative radiotherapy.
The phase II component will be closed once approximately 120 patients are recruited and all necessary approvals for protocol version 4.0 implementing the phase III design are obtained. Target recruitment rates are ≥4 and ≥6 patients randomised per month at 12 and 24 months respectively for total accrual of 120 international cases. Each individual country will attempt to exceed the minimum recruitment required to sustain phase III (UK 75, the Netherlands 75, Denmark 30). If recruitment is on target in year two then consideration will be given to an early application for transition to phase III with a funding application and a formal protocol amendment.

Phase III:
International, multi-centre, open-label, rolling phase II/III trial with a partially randomised patient preference design. Patients will choose organ preservation or standard surgery. Those who prefer organ preservation will be randomised 1:1 between:
1. Organ preservation with mesorectal CRT. Capecitabine: 825 mg/m² orally, b.d., on radiotherapy days . Radiotherapy: A dose of 50 Gy applied to the primary tumour and surrounding mesorectum in 25 fractions of 2 Gy, 5 days a week.
2. Organ preservation with mesorectal SCRT. A dose of 25 Gy applied to the primary tumour and surrounding mesorectum in 5 fractions of 5 Gy, 5 days a week.
Those who prefer standard surgery or have no preference will undergo standard TME surgery without neoadjuvant radiotherapy treatment.

Phase II and III:
For organ-preserving strategies, clinical response to radiotherapy determines the next treatment step. Radiotherapy response is evaluated using clinical exam, endoscopy and MRI. The first assessment at 11-13 weeks (from radiotherapy start) using composite clinical, endoscopic and MRI based assessment will identify a minority of non-responders who should convert to TME surgery. Patients demonstrating a satisfactory radiotherapy response at 11-13 weeks will be reassessed by endoscopy at 16-20 weeks.

Re-evaluation at 16-20 weeks determines if the STAR-TREC criteria for complete response (CR) are met. Patients who achieve CR may progress directly to active surveillance. Those who do not fulfil the criteria for CR will progress to excision biopsy with TEM.

Previous interventions:
After all eligibility criteria have been confirmed and following informed consent, which will be conducted in accordance with Good Clinical Practice standards, and completion of the baseline assessments, patients will be randomised to one of three groups in a 1:1:1 basis using a computer-generated program at the Birmingham Clinical Trials Units (BCTU).

Group 1: Participants undergo conventional TME surgery. This will encompass both reconstructive and non-reconstructive approaches to rectal resection using the principles of TME surgery. The former includes low anterior resection, the latter abdominoperineal excision or low Hartman's procedure. Surgeons may use either a laparoscopic, robotic or open approach to surgery. Hybrid approaches (combined laparoscopic and open) are also permitted. The quality of surgery will be measured using a standardised histopathological assessment that grades whether surgery was performed according to the principles of TME.

Group 2: Participants undergo organ using long course concurrent chemoradiation (CRT). This involves concurrent chemoradiotherapy consisting of treatment with capecitabine, administered at a dose of 825 mg/m2 bid on days of radiotherapy treatment (excluding weekend days when patients do not undergo radiotherapy treatment). Capecitabine is taken orally twice a day in equal doses for 5 days per week (normally Monday – Friday), on the days of radiotherapy administration only, throughout the 5 week course of radiotherapy. If radiotherapy is not given (e.g. due to machine maintenance or bank holiday), then capecitabine should not be given that day either. Capecitabine treatment can begin on any day of the week; however, there is normally no capecitabine treatment on Saturday or Sunday, unless radiotherapy is given on one of these days. Patients are asked to take capecitabine with a glass of water each day within 30 minutes after the ingestion of food (ideally after breakfast and evening meals), commencing the morning of the first dose of radiotherapy treatment. If patients have difficulty swallowing tablets, it is possible to dissolve the tablets in approximately 200 ml of lukewarm water. There is no stability data for any form of capecitabine suspension, so this should be done immediately prior to use and the solution swallowed immediately, rinsing to ensure all of the suspension has been ingested. As the solution has a bitter taste, flavouring with a fruit juice or squash (except grapefruit juice) is allowed.

Group 3: Participants undergo organ using short course radiotherapy (SCPRT). This involves a dose of 25Gy, applied, to the primary tumour and surrounding mesorectum in 5 fractions of 5 Gy, 5 days a week. A total dose of 25 Gy in 5 daily fractions over a total time of 1 week should be delivered, treating 5 days per week, 1 fraction per day, using 5 Gy per fraction.

For participants in group 1, surgical morbidity will be recorded post-operatively until 30 days after surgery. Follow-up after standard TME surgery will differ significantly compared to the organ preserving strategies. Both will include regular clinical follow-up as per usual national practice. Each centre can perform additional visits, endoscopies or imaging as per national protocol or patient/doctors preference. The minimal required follow-up after TME surgery will be at 30-days post-operatively and then 3, 6 12, 24 and 36 months after TME surgery and is detailed in the protocol. CT of chest-abdomen is required in order to have a reliable disease free survival of all patients in this study after 24 months. CT or MRI pelvis is also required in order to have a reliable pelvic recurrence rate of all patients in this study after 24 months. The information routinely recorded in normal clinical notes should be sufficient for completion of the annual follow-up case report forms.

For participants in groups 2 and 3, radiotherapy vwill be administered as per protocol and radiotherapy delivery and toxicities up to 3 weeks after the completion of radiotherapy will be recorded. Follow-up after (chemo)radiotherapy will include regular follow-up as per usual practice. To monitor the need for local excision, radical surgery or watchful waiting, mucosal or lymph node recurrence should be carefully monitored and additional examinations are mandatory as listed below. If patients are treated with radical surgery (TME) the follow-up schedule as described in above for patients in group 1 , 'Clinical assessments and follow-up after TME surgery' will be used. In the first year, all organ preserved patients will undergo a MRI and endoscopy every 3 months. CT of chest-abdomen is required in order to have a reliable disease free survival of all patients in this study after 24 months. The information routinely recorded in normal clinical notes should be sufficient for completion of the annual follow-up case report forms. If patients will undergo TME surgery because of incomplete response after (chemo) radiation therapy or in case of recurrence, follow up will be performed at 3, 4.5, 6, 9, 12, 18, 24 and 36 months after (Chemo) Radiation Therapy and specifics are detailed in the protocol.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measure as of 28/06/2021:
Phase II:
Recruitment rate measured by recording the number of eligible participants who consent to participate in the trial at 12 and 24 months.

Phase III:
Proportion of patients who prefer organ preservation with successful organ preservation measured by recording the number of participants with an in-situ rectum (includes patients subject to transanal local resection), no defunctioning stoma, and an absence of active loco-regional cancer failure at 30 months from the first day of (chemo)radiotherapy treatment

Previous primary outcome measure:
Recruitment rate is measured by recording the number of eligible participants who consent to participate in the trial at 12 and 24 months.

Key secondary outcome(s))
Current secondary outcome measures as of 28/06/2021:
Phase II:
1. Procurement of STAR-TREC funding by one international partner
2. Opening of STAR-TREC by one international partner
3. Efficacy of organ preserving treatment arm on completion of phase II study measured by the organ saving rate at 12 months (following randomisation) in the experimental arms, where efficacy is defined as an organ saving rate of >50%.
4. Additional outcome measures pertinent to a future phase III study examining the safety and efficacy of organ saving versus standard surgery will also be collected:
4.1. Safety will be assessed using:
4.1.1. Accuracy of MRI in predicting STAR-TREC eligibility
4.1.2. 30-day mortality
4.1.3. 6 month mortality
4.1.4. Surgical morbidity
4.1.5. Rate of tumour recurrence or regrowth within the bowel wall (experimental arm)
4.1.6. Rate of tumour recurrence within the mesorectum (experimental arm)

4.1.7. Rate of distant metastases
4.1.8. Pelvic failure rate: expressed as a sum of the following unresectable pelvic tumour, cases requiring beyond TME surgery, or tumour recurrence or regrowth ≤1mm from the circumferential surgical margin after TME surgery.
4.1.9. Bowel, bladder and sexual dysfunction (measured by EORTC QLQ CR29 & C30, LARS score, and ICIQ-MLUTS/ICIQ-FLUTS) at 12 and 24 months compared to baseline.
4.2. Efficacy will be assessed using:
4.2.1. Proportion of patients with/ without a stoma at 30 days and one year
4.2.2. Histopathological assessment of tumour down-staging following radiotherapy according to depth of tumour invasion and the incidence of other high-risk features in comparison to non-irradiated (control) group
4.2.3. Proportion of patients identified by clinical and MRI assessment as suitable for active monitoring
4.2.4. Conversion rates from organ saving to radical surgery
4.2.5. Disease free survival
4.2.6. Quality of life (measured by EORTC QLQ CR29 & C30, EuroQol EQ-5D, LARS score and ICIQ-MLUTS/ICIQ-FLUTS) at 12 and 24 months compared to baseline.
4.2.7. Overall survival

Phase III:
Secondary outcomes for the randomised comparison between organ-preserving strategies:
1. Clinician-reported acute treatment related toxicity up to 30 days following completion of (chemo)radiotherapy
2. Proportion of patients with CR to (chemo)radiation therapy
3. Proportion of patients undergoing transanal local excision
4. Time to event of organ loss assessed for patients who prefer organ preservation; defined as the length of time from the start date of trial treatment until TME surgery
5. Non-regrowth pelvic tumour control to 36 months; defined as the length of time from the start date of trial treatment until death (any cause) or development of unequivocal pelvic recurrence but not including patients who developed local regrowth which was resected with clear margins using standard TME surgery
6. Metastasis free survival to 36 months; defined as the length of time from the start date of trial treatment until death (any cause) or detection of distant metastasis
7. Non-regrowth -disease free survival to 36 months; defined as the length of time from the start of trial treatment until death (any cause), detection of local pelvic recurrence or distant metastasis but not including patients who developed local regrowth which was resected with clear margins using standard TME surgery
8. Overall survival to 60 months defined as the length of time from the start date of trial treatment until death (any cause)

Secondary endpoints for analyses incorporating the standard surgery comparator (phase II: randomised comparison; phase III: non-randomised comparison):
1. Clinician-reported acute treatment related toxicity up to 30 days following completion of (chemo)radiotherapy or date of initial surgery
2. Non-regrowth pelvic tumour control to 36 months; defined as the length of time from the start date of (chemo)radiotherapy or date of initial surgery until death (any cause) or development of unequivocal pelvic recurrence but not including patients who preferred organ preservation and developed local regrowth which was resected with clear margins using standard TME surgery
3. Metastasis-free survival to 36 months; defined as the length of time from the start date of trial treatment or date of initial surgery until death (any cause) or detection of distant metastasis
4. Disease-free survival to 36 months; defined as the length of time from the start date of trial

treatment or date of initial surgery until death (any cause), detection of local pelvic recurrence or distant metastasis but not including patients who developed local regrowth which was resected with clear margins using standard TME surgery
5. Overall survival to 60 months defined as the length of time from the start date of trial treatment or date of initial surgery until death (any cause)
6. Decision regret measured using the validated Decision regret scale questionnaire/Treatment decision questionnaire at 24 months. The Decision Regret Scale is a 5-item Likert-type measure written to assess regret or remorse following a medical decision that takes less than 5 minutes to complete. High scores suggest high regret over a health care decision. Scores may be transformed to a scale of 0 (no regret) to 100 (high regret).

Secondary endpoint for analyses of patient-reported outcomes including symptomatic toxicity and health-related quality of life (HRQoL).
1. Patient-reported symptomatic toxicity, health economics and HRQoL, measured using the following questionnaires at baseline (after informed consent is obtained but before trial entry), 3, 12, 24, and 36 months after the start of trial-specific treatment:
1.1. European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30, a 30-item questionnaire developed by the European Organization for Research and Treatment to assess generic aspects of QoL of cancer patients; such as physical, psychological, and social functions. It is composed of 5 multi-item scales (physical, role, social, emotional and cognitive functioning) and 9 toxicity related single items.
1.2. The Colorectal Cancer Module developed by the European Organization for Research and Treatment (EORTC QLQ-CR29) is used in conjunction with the EORTC QLQ-C30 to assess quality of life in patients with colorectal cancer.
1.3. The EuroQol 5-dimension 3-level questionnaire (EuroQoL EQ-5D-3L) collects information about five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety /depression and is the standard questionnaire used in health economic evaluation. The results can be combined into a 5-digit number that describes the patient's health state which in turn can be assigned a utility score. The questionnaire also includes a visual analogue scale to record the patient's self-rated health on a vertical visual scale.
1.4. The International Consultation on Incontinence Modular Questionnaire on Male Lower Urinary Tract Symptoms (ICIQ-MLUTS) is a questionnaire for evaluating male lower urinary tract symptoms and impact on quality of life composed of 13 items which was derived from the fully validated ICSmaleSF questionnaire.
1.5. The International Consultation on Incontinence Modular Questionnaire on Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) is a validated questionnaire for evaluating female lower urinary tract symptoms and impact on quality of life composed of 12 items which was derived from the fully validated BFLUTS-SF questionnaire.
1.6. Low Anterior Resection Syndrome (LARS) Score is a validated, concise and easy-to-use questionnaire for assessment of bowel dysfunction following a sphincter-preserving low anterior resection with or without radiotherapy for rectal cancer. The results distinguish 3 clinically meaningful severity categories ("no LARS," "minor LARS," and "major LARS").
2. Analysis of patient-reported symptomatic toxicity and HRQoL health-related quality of life at 3, 12, 24, and 36 months compared to baseline will be conducted incorporating the following comparisons:
2.1. Randomised comparison between organ-preserving strategies
2.2. Randomised (phase II data) and non-randomised (phase III data) comparisons between organ preserving strategies and the standard surgery comparator

Previous secondary outcome measures:
1. Ability of a single international partner to procure independent funding in year 1 is assessed through seeing whether the study being carried out internationally

2. Ability of a single international partner to open the study to recruitment in year 1 is assessed through seeing whether the study being carried out internationally
3. Organ saving rate in the experimental arms at 12 months (from randomisation) is assessed through review of data collected on the annual follow-up form
4. Proportion of patients undergoing TME surgery accurately staged and satisfying inclusion/ exclusion criteria is assessed through the MRI data collected at baseline
5. Proportion of patients identified by MRI suitable for active monitoring based on mrTRG assessment is assessed through the MRI data collected at baseline
6. Three-year pelvic failure rate defined as the proportion of patients in each arm with:
6.1. Unresectable pelvic tumor
6.2. Uelvic tumour requiring beyond TME surgery
6.3. ≤1mm circumferential resection margin after TME surgery
and is assessed through the data collected on the 36-month annual follow-up for and also the 36 Month MRI scan
7. Overall survival is assessed through the annual follow-up at 12, 24, and 36 months
8. Stoma free survival is assessed through the annual follow-up form at 30 days and 12 months post-surgery
9. Health Related Quality of Life (HR QoL) measured by EORTC QLQ CR29 & C30, EuroQoL EQ-5D will be assessed baseline and 12, 24 months post randomisation
10. Bowel, bladder, and sexual dysfunction measured by LARS score and ICIQ-MLUTS/ICIQ-FLUTES will be assessed baseline and 12, 24 months post randomisation

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 28/06/2021:
1. Biopsy proven adenocarcinoma of the rectum
2. MRI-defined ≤T3b (with ≤5mm of mesorectal invasion) rectal tumour or endorectal ultrasound-defined ≤uT3b rectal cancer (optional: in centres where high quality endorectal ultrasound (ERUS) is available or patient unable to tolerate MRI)
3. MDT determines that all of the treatment options TME surgery, CRT, SCPRT, and TEM are feasible
4. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
5. Able and willing to provide written informed consent for the study

For patients choosing organ preservation only:
1. If female and of childbearing potential must fulfil both of the following:
1.1. Have a negative pregnancy test within 7 days prior to study entry
1.2. Agree to use adequate, medically approved, contraceptive precautions from trial entry until 6 months after the end of study treatment
2. If a non-sterilised male with a partner of childbearing potential, must agree to use adequate, medically approved, contraceptive precautions from trial entry until 6 months after the end of study treatment

Previous participant inclusion criteria:
1. Biopsy proven adenocarcinoma of the rectum
2. mriT1-3bN0 (with ≤5mm of mesorectal invasion) rectal tumour or endorectal ultrasound defined rectal cancer uT1- uT3b (optional: in centres where high quality ERUS is available and

patient unable to tolerate MRI)
3. MDT determines that all of the following treatment options are feasible: (a) TME surgery, (b) CRT (c) SCPRT d) TEM Patients with equivocal radiological lesions e.g. mesorectal, retroperitoneal, liver, lung are eligible if agreed by MDT
4. Aged 16 or over in UK (18 or over in the Netherlands and Denmark).
5. Estimated creatinine clearance >50 mls/min
6. Absolute neutrophil count >1.5x109/l; platelets >100 x 109/L
7. Serum transaminase

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
Current participant exclusion criteria as of 28/06/2021:
1. Concomitant or previous malignancies within 3 years prior to trial entry, except those that in the opinion of the MDT are unlikely to relapse within 3 years or lead to death within 5 years
2. Unequivocal evidence of metastatic disease (includes resectable metastases). Patients with equivocal radiological lesions (e.g. retroperitoneal, liver, lung) that are not classified as M1 are eligible if agreed by MDT.
3. MRI node positive (≥N1, defined by protocol guidelines)
4. MRI extramural vascular invasion (mriEMVI) positive (defined by protocol guidelines)
5. MRI defined mucinous tumour
6. Mesorectal fascia threatened (≤1 mm on MRI or ERUS)
7. Maximum tumour diameter >40 mm (either measured from everted edges on sagittal MRI or on ERUS)
8. Tumour position anterior, above the peritoneal reflection on MRI or EUS
9. No residual luminal tumour following endoscopic resection
10. Contraindications to radiotherapy including previous pelvic radiotherapy
11. Uncontrolled cardiorespiratory comorbidity (includes patients with inadequately controlled angina or myocardial infarction or arrhythmia within 6 months prior to randomisation)
12. Known dihydropyrimidine dehydrogenase (DPYD) deficiency
13. Known Gilberts disease (hyperbilirubinaemia)
14. Taking coumarin-derivative anticoagulants (e.g. warfarin) that cannot be discontinued at least 7 days prior to starting treatment or substituted by low molecular weight heparin
15. Taking phenytoin or sorivudine or its chemically related anologues, such as brivudine, within 4 weeks of trial entry (see Section 8.3.5 for further details)
16. Taking metronidazole at study entry

17. Pregnant or lactating
18. History of severe and unexpected reactions to fluoropyrimidine therapy
19. Aged <16 years (UK) or <18 years (other countries)

Previous participant exclusion criteria:
1. Unequivocal evidence of metastatic disease (includes resectable metastases)
2. MRI node positive (defined by protocol guidelines)
3. MRI extramural vascular invasion (mriEMVI) positive (defined by protocol guidelines)
4. MRI defined mucinous tumour
5. Mesorectal fascia threatened (< 1 mm on MRI)
6. Maximum tumour diameter > 40mm as measured from everted edges on sagittal MRI
7. Tumour position anterior, above the peritoneal reflection on MRI or EUS
8. No residual luminal tumour following endoscopic resection
9. Contraindications to radiotherapy including previous pelvic radiotherapy
10. Uncontrolled cardiorespiratory comorbidity (includes patients with inadequately controlled angina or myocardial infarction within 6 months prior to randomisation)
11. Known dihydropyrimidine dehydrogenase (DPYD) deficiency
12. Known Gilberts disease (hyperbilirubinaemia)
13. Taking warfarin that cannot be discontinued at least 7 days prior to starting treatment or substituted by low molecular weight heparin
14. Taking phenytoin or sorivudine or its chemically related anologues, such as brivudine (see Section 8.4.5 for further details)
15. Pregnant, lactating or pre-menopausal women not using adequate contraception
16. Unable or unwilling to provide written informed consent

Date of first enrolment
01/11/2016

Date of final enrolment
31/12/2023

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Denmark

Netherlands

Study participating centre
Cardiff & Vale Health Board
University Hospital of Wales

Heath Park Way
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

Previous publication and dissemination plan:
A meeting will be held after the end of the study to allow discussion of the main results among the collaborators prior to publication. The success of STAR-TREC depends on the collaboration of a large number of clinicians across several countries. For this reason, all publications arising from this work will be attributed to the 'STAR-TREC Collaborative Group'.
Publications will conform with the ICMJE guidelines (December 2015). When manuscripts are submitted, the corresponding author will specify the name of the STAR-TREC group, and clearly identify the group members who can take credit and responsibility for the work as authors. The byline will include the STAR-TREC name and allow MEDLINE to list the names of individual group members who are authors or who are collaborators. There will be a note associated with the byline clearly stating that the individual names are elsewhere in the paper and whether those names are authors or collaborators.
In this way, all contributors to the STAR-TREC study will be recognised.
The Trial Management Group must review any secondary publications and presentations prepared by Investigators. Authors must acknowledge that the trial was performed with the support of the funders and The University of Birmingham as study Sponsor.
Further publication details to be confirmed and will be provide in due course at a later date.

IPD sharing statement:
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/12/2017		Yes	No
Protocol article		24/03/2022	14/11/2022	Yes	No
Other publications	radiotherapy quality assurance	18/02/2020	28/06/2021	Yes	No
Other publications	rationale behind radiotherapy treatment target volume	04/02/2020	28/06/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes