

Transanal endoscopic microsurgery (TEM) and Radiotherapy in Early rectal Cancer

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
15/07/2009	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
09/11/2009	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
21/11/2022	Cancer	

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-possible-new-way-treat-cancer-back-passage-trec>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

1.0

Study information

Scientific Title

Transanal endoscopic microsurgery (TEM) and Radiotherapy in Early rectal Cancer: a randomised phase II feasibility study

Acronym

TREC

Study objectives

TREC will determine the feasibility of performing a randomised controlled trial (RCT) of radical total mesorectal excision (TME) surgery (current gold standard) versus short course pre-operative radiotherapy (SCPRT) and delayed local excision at 8 - 10 weeks for T1-2N0M0 rectal cancer defined according to both magnetic resonance imaging (MRI) and endorectal ultrasound (ERUS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised open label phase II feasibility study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Early rectal cancer

Interventions

A phase II open, multi-centre randomised controlled trial for patients with early rectal cancer comparing:

1. Conventional TME surgery
2. Short course pre-operative radiotherapy (SCPRT) and delayed local excision with TEM (after an 8 - 10 week interval)

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

Recruitment, measured at 12, 18 and 24 months

Key secondary outcome(s)

1. Safety:
 - 1.1. 30-day mortality
 - 1.2. 6-month mortality

1.3. Surgical morbidity

1.4. Bowel, bladder and sexual function (measured by European Organization for Research and Treatment of Cancer Quality of Life Questionnaires [EORTC QLQ] C29 and C30)

2. Efficacy:

2.1. Histopathological assessment of tumour down-staging according to depth of tumour invasion and the incidence of other high-risk features

2.2. Conversion rates from organ conservation to radical surgery

Completion date

01/12/2011

Eligibility

Key inclusion criteria

1. Biopsy proven adenocarcinoma
2. MRI defined stage I rectal cancer (less than or equal to pT2 N0)
3. Endorectal ultrasound defined rectal cancer less than or equal to uT2
4. Patients who have undergone submucosal excision for a presumed villous adenoma that on histopathological examination contains discrete invasion less than 3 cm diameter
5. Aged 18 or over, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

55

Key exclusion criteria

1. Familial/genetic cancer
2. T3+ or nodal involvement on radiological staging
3. Contraindications to radiotherapy
4. Previous pelvic radiotherapy
5. Metastatic disease
6. Unable or unwilling to provide written informed consent

Date of first enrolment

01/12/2009

Date of final enrolment

01/12/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

The University of Birmingham

Birmingham

United Kingdom

B15 2TH

Sponsor information

Organisation

University of Birmingham (UK)

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (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

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	16/12/2020	Yes	No
Results article	Quality of life	17/11/2022	21/11/2022	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