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

Submission date 15/07/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/11/2009	**Overall study status** Completed	
Last Edited 21/11/2022	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-possible-new-way-treat-cancer-back-passage-trec

Study website
https://www.TREC.bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Recruitment, measured at 12, 18 and 24 months

Secondary outcome measures
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

Overall study start date
01/12/2009

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 submuscosal 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

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Target of 46 participants for the pilot phase

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
England

United Kingdom

Study participating centre
The University of Birmingham
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details

Research & Enterprise
Edgbaston
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Sponsor type
University/education

Website
http://www.bham.ac.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, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

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