

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

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

## 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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### Contact details

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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?
<a href="#">Results article</a>	results	01/02/2021	16/12/2020	Yes	No
<a href="#">Results article</a>	Quality of life	17/11/2022	21/11/2022	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes