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A 2 x 2 randomised, double blind, placebo controlled trial of pentoxifylline (trental) +/high dose vitamins for radiation induced bowel toxicity: the ROBOTS 2 trial

Submission date 30/09/2005	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 30/09/2005	Overall study status Completed	 Statistical analysis plan Results
Last Edited 18/11/2013	Condition category Injury, Occupational Diseases, Poisoning	 Individual participant data Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0258134912

Study information

Scientific Title

Acronym ROBOTS 2 (Relief Of BOwel Toxicity Study 2)

Study objectives

This would be the first randomised trial addressing this issue in patients with bowel symptoms after radiotherapy.

Ethics approval required Old ethics approval format

Ethics approval(s) Not provided at time of registration

Study design Randomised controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Injury, Occupational Diseases, Poisoning: Radiation injuries

Interventions

Patients will be randomised in a 2 x 2 factorial fashion to:
1. Pentoxifylline (trental)
2. High dose vitamins
3. Pentoxifylline (trental) with high dose vitamins
4. Placebo

Intervention Type Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pentoxifylline (trental), high dose vitamins

Primary outcome measure

1. Changes in the bowel toxicity scale Inflammatory Bowel Disease Questionnaire (IBDQ) 2. Changes in the Vaizey incontinence questionnaire

Secondary outcome measures

Not provided at time of registration

Overall study start date 26/03/2004

Completion date 13/04/2008

Eligibility

Key inclusion criteria

- 1. Patients referred at least three months after pelvic radiotherapy
- 2. Patients must have gastrointestinal symptoms which were not present before radiotherapy
- 3. Must have undergone adequate gastroenterological assessment to reach a diagnosis
- 4. Must have residual gastrointestinal symptoms after three months of best therapy

Participant type(s)

Patient

Age group Not Specified

Sex Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

- 1. Previous cerebrovascular haemorrhage
- 2. Previous retinal haemorrhage
- 3. Liver cirrhosis
- 4. Symptomatic coronary artery disease
- 5. Abnormal renal function and creatine clearance
- 6. History of renal tract stone
- 7. Evidence of recurrent disease

Date of first enrolment

26/03/2004

Date of final enrolment 13/04/2008

Locations

Countries of recruitment England

United Kingdom

Study participating centre Medicine Section Sutton, Surrey United Kingdom SM2 5PT

Sponsor information

Organisation Department of Health

Sponsor details

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Sponsor type

Government

Website http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type Government

Funder Name The Royal Marsden NHS Foundation Trust (UK)

Funder Name NHS R&D Support Funding (UK)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary Not provided at time of registration