ISRCTN33398289 https://doi.org/10.1186/ISRCTN33398289

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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 18/11/2013	**Condition category** Injury, Occupational Diseases, Poisoning	

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
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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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