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	Condition category	Individual participant data
18/11/2013	Injury, Occupational Diseases, Poisoning	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Injury, Occupational Diseases, Poisoning: Radiation injuries

Interventions

Patients will be randomised in a 2×2 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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre Medicine Section

Sutton, Surrey

Sponsor information

Organisation

Department of Health

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration