

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	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/11/2013	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Primary study design

Interventional

Study design

Randomised controlled trial

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 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(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

United Kingdom
SM2 5PT

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