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Randomised controlled trial of Normacol for faecal incontinence after pelvic radiotherapy

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** Signs and Symptoms	[ ] 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
N0258127574

Study information

Scientific Title

Study objectives
To determine the effectiveness of normacol for treating faecal incontinence.

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
Faecal incontinence

Interventions
Normacol versus placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Normacol

Primary outcome measure
Would be the first study of any kind to report benefit for any treatment in this group of patients with this condition.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2003

Completion date
30/05/2007

Eligibility

Key inclusion criteria
Any patient with episodes of active or passive faecal incontinence one or more per month at least 3 months after the completion of pelvic radiotherapy who did not have pre-existing incontinence.

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. Patients unlikely to survive 1 year
2. Patients unable to give informed consent

Date of first enrolment
01/07/2003

Date of final enrolment
30/05/2007

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
Richmond House
79 Whitehall
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SW1A 2NL
+44 (0)20 7307 2622
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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