

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

Contact name
Dr Jervoise Andreyev

Contact details
Medicine Section
Royal Marsden NHS Trust
Downs Road
Sutton, Surrey
United Kingdom
SM2 5PT
+44 (0)20 8643 8901

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

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