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The use of misoprostol suppositories to reduce radiotherapy-induced anorectal dysfunction

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 28/07/2017	**Condition category** Digestive System	

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
N0263115181

Study information

Scientific Title
The use of misoprostol suppositories to reduce radiotherapy-induced anorectal dysfunction

Study objectives
What are the long-term structural and functional changes in the anorectum following pelvic radiotherapy for prostate cancer, can they be prevented by the use of misoprostol suppositories?

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
Acute radiation proctitis

Interventions
Randomised controlled clinical trial:
1. Misoprostol suppositories
2. Placebo

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure

A reduction in acute radiation proctitis symptoms.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2002

Completion date
01/10/2005

Eligibility

Key inclusion criteria
50 patients from oncology

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
50

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/2002

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

The Middlesex Hospital
London
United Kingdom
W1N 8AA

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University College London Hospitals NHS Trust (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