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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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
A reduction in acute radiation proctitis symptoms.

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/10/2005

Eligibility

Key inclusion criteria
50 patients from oncology

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
The Middlesex Hospital
London
United Kingdom
W1N 8AA

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
University College London Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration