

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/07/2017	Condition category Digestive System	<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

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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