OSL Belly Board in patients receiving pelvic radiotherapy for rectal cancer

Submission date	Recruitment status No longer recruiting Overall study status	 Prospectively registered 	
29/09/2006		Protocol	
Registration date		Statistical analysis plan	
29/09/2006	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
05/05/2016	Cancer		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0013164858

Study information

Scientific Title

OSL Belly Board in patients receiving pelvic radiotherapy for rectal cancer

Study objectives

As part of our service development programme to improve patient immobilisation systems for the delivery of radiotherapy with new techniques we want to investigate a belly board system for our patients treated in the prone position for Rectal Cancer. The principle questions are whether the belly board will improve the reproducibility of the patient's position and reduce the amount of small bowel within the radiation fields.

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer: Rectal

Interventions

A randomised trial designed to test the null hypothesis 'whether the Belly Board will improve the reproducibility of the patient's position and reduce the amount of small bowel within the radiation fields'.

25 patients will be randomised to be treated on the Board and 25 patients recruited as controls. Patients in the Belly Board arm of the study will need two CT scans, one on the Board to plan their treatment and one in the normal position so that the amount of small bowel in the radiation field can be compared within the same patient in the two different positions.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. The reproducibility of the patients position in our standard prone set up compared with that using the Belly Board
- 2. The small bowel volume within the radiation fields in our standard prone set up compared with that using the Belly Board

Secondary outcome measures

- 1. To compare the patient comfort and ease of set up using our standard prone set up compared with that using the Belly Board
- 2. To compare the acute toxicity of radiotherapy delivered using our standard prone set up with that using the Belly Board

Overall study start date

01/03/2005

Completion date

30/09/2006

Eligibility

Key inclusion criteria

50 patients who have histopathologically confirmed, resectable Rectal Adenocarcinoma who will be undergoing pelvic radiotherapy.

Inclusion criteria are:

- 1. Histopathology confirmed, resectable rectal adenocarcinoma
- 2. No prior pelvic radiotherapy
- 3. Staging CT Chest Abdomen and Pelvis excludes metastases
- 4. MRI staging T3/4 or N1 or T2 lower third rectal tumours
- 5. Age > 18
- 6. KPS > 70 and independently mobile to get onto the belly board
- 7. No contraindications to 5FU chemotherapy
- 8. Informed consent obtained
- 9. Subject able to fit into CT scanner on belly board

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

25 patients active (belly board) and 25 patients as controls.

Key exclusion criteria

Not meeting any of the inclusion criteria.

Date of first enrolment

01/03/2005

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St Thomas' Hospital London United Kingdom SE1 7EH

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK), NHS R&D Support Funding

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No