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OSL Belly Board in patients receiving pelvic radiotherapy for rectal cancer

Submission date	Recruitment status	[_] Prospectively registered
29/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] 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

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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
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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