

OSL Belly Board in patients receiving pelvic radiotherapy for rectal cancer

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

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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