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Computed tomography (CT)-guided intervention with and without fluoroscopic control: what are the benefits for the patient and the doctor?

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/07/2016	**Condition category** Surgery	[_] Individual participant data [_] 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
N0050149623

Study information

Scientific Title
Computed tomography (CT)-guided intervention with and without fluoroscopic control: what are the benefits for the patient and the doctor?

Study objectives
Does the introduction of fluoroscopy in computed tomography (CT)-guided intervention decrease procedure time and dose exposure and does it make the procedure technically easier and improve outcome?

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Computed tomography-guided interventions

Interventions
All patients attending for CT-guided interventions (biopsies and drainages) are invited to take part. Patients randomised to have procedure in conventional manner with CT guidance (controls) or with additional fluoroscopy. Time taken to have procedure, effective dose to patient, operator and assistant, patient comfort and acceptability, number of passes /complications and degree of technical success measured.

Intervention Type

Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Dose product to patient
2. Effective dose to patient
3. Effective dose to doctor and nurse/assistant
4. Hand dose to doctor
5. Screening time
All measured using electronic dose meters

6. Comfort and acceptability Questionnaire
7. BIOPSY - Number of passes, complications and diagnostic specimens
8. DRAINAGES - Number of passes, Complications and Technical success

Secondary outcome measures
No secondary outcome measures

Overall study start date
28/05/2004

Completion date
28/11/2004

Eligibility

Key inclusion criteria
All adult in-patients and out-patients attending for CT guided biopsies and drainages

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Acute emergency cases
2. Inability to give informed consent
3. Unconscious patients

Date of first enrolment
28/05/2004

Date of final enrolment
28/11/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bradford Royal Infirmary
Bradford
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name

Bradford Teaching Hospitals NHS Foundation Trust (UK)

Funder Name
Own account funding (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