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The diagnostic and therapeutic impact of early computer tomography (CT) in patients with pleuritic chest pain

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 13/04/2018	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nicholas Screaton

Contact details
Department of Radiology
Box 219
Addenbrooke's NHS Trust
Hills Road
Cambridge
United Kingdom
CB2 2QQ
+44 (0)1223 216516
nickscreaton@hotmail.com

Additional identifiers

Protocol serial number
N0544116605

Study information

Scientific Title
The diagnostic and therapeutic impact of early computer tomography (CT) in patients with pleuritic chest pain: a randomised study

Study objectives
We hypothesise that early contrast-enhanced spiral CT will expedite diagnosis and initiation of appropriate treatment and therefore reduce hospital stay.
Primary objective: to assess the impact of early CT on duration of hospital stay.
Supplementary objectives: to assess the impact of early CT on diagnosis, diagnostic confidence, therapy, patient satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Respiratory: Pleuritic chest pain

Interventions
All patients admitted between midnight on Sunday and midday on Friday under the care of the on-call general medical teams or medical admissions unit (MAU) with acute onset of pleuritic chest pain will be considered for inclusion. Consenting patients fulfilling the inclusion criteria will be randomised to either routine practice or early CT. Patients in whom urgent CT is considered necessary as part of routine practice, those under age 18 or with a contraindication to contrast medium administration will be excluded. If deemed clinically necessary patients randomised to the routine practice arm may subsequently be referred for CT.

The admitting medical Specialist Registrar will complete an admission questionnaire recording the working diagnosis, diagnostic confidence and the proposed treatment prior to investigation.

Patients randomised to early CT will undergo a spiral CT pulmonary angiogram within 24 h of admission, performed between 9 am and 5 pm Monday to Friday. The chest will be imaged during intravenous non-ionic contrast medium administration (130 ml [iopamidol 300]). The supervising radiologist will record a provisional report in the patient¿s hospital notes, and dictate a formal report.

A follow-up questionnaire will be distributed to the admitting clinician for completion 24 h after admission in order to determine the working diagnosis and proposed management at that stage. Patients will be asked to complete a patient satisfaction questionnaire 48 h after admission.

Three months following discharge, patient's hospital records will be reviewed in order to determine the final diagnosis, number and timings of inpatient investigations and any complications.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Duration of hospital stay

Key secondary outcome(s)
Impact of early CT on diagnosis, diagnostic confidence, therapy, patient satisfaction.

Completion date
29/08/2003

Eligibility

Key inclusion criteria
1. 75 subjects aged 18-95 years
2. Admitted between midnight on Sunday and midday on Friday under the care of the on-call general medical teams or medical admissions unit (MAU) with acute onset of pleuritic chest pain
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Lower age limit
18 Years

Upper age limit
95 Years

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
20/09/2002

Date of final enrolment
29/08/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrookes (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration