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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

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 measure
Duration of hospital stay

Secondary outcome measures
Impact of early CT on diagnosis, diagnostic confidence, therapy, patient satisfaction.

Overall study start date
20/09/2002

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

Age group

Other

Lower age limit
18 Years

Upper age limit
95 Years

Sex
Both

Target number of participants
75

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London

United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrookes (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