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The Christopher Study: effective management of pulmonary embolism by clinical decision rule (CDR), D-dimer test and helical computed tomography (CT)

Submission date
04/04/2006

Recruitment status
No longer recruiting

Registration date
04/04/2006

Overall study status
Completed

Last Edited
05/11/2008

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR581

Study information

Scientific Title

Acronym
Christopher Study

Study objectives
It is safe to withhold anticoagulant treatment in patients with clinically suspected pulmonary embolism (PE) who have either a combination of clinical decision rule (CDR) indicating PE unlikely and normal D-dimer test or CDR indicating PE likely or abnormal D-dimer test and normal helical computed tomography (CT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The institutional review boards of all participating hospitals approved the study protocol.

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Pulmonary embolism (PE)

Interventions
Diagnosis of PE by CDR, D-dimer and helical CT.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Thromboembolic disease during three months follow-up in all patients.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/11/2002

Completion date
01/12/2004

Eligibility

Key inclusion criteria
Adult patients more than 18 years old with clinically suspected pulmonary embolism.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3306

Key exclusion criteria
1. Pregnancy
2. Allergy to contrast media
3. No geographic possibility of return for follow-up
4. Treatment with therapeutic heparin for more than 24 hours
5. Indication for thrombolytic therapy

Date of first enrolment
01/11/2002

Date of final enrolment
01/12/2004

Locations

Countries of recruitment

Netherlands

Study participating centre
Leiden University Medical Centre (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Amphia Hospital Breda (The Netherlands)

Funder Name
Hospital Hilversum (The Netherlands)

Funder Name
University Hospital Maastricht (AZM) (The Netherlands)

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Funder Name
Erasmus Medical Centre (The Netherlands)

Funder Name
University Medical Centre St Radboud (The Netherlands)

Funder Name
Meander Medical Centre (The Netherlands)

Funder Name
Spaarne Hospital (The Netherlands)

Funder Name
Diakonessenhuis Meppel (The Netherlands)

Funder Name
Medical Centre Rijnmond, location Zuider Hospital Rijnstate Hospital (The Netherlands)

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	11/01/2006		Yes	No