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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
04/04/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
04/04/2006	Completed	[X] Results		
<b>Last Edited</b> 05/11/2008	Condition category Circulatory System	[] 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

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