Prometheus Perfusion Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20532

Source
Nationaal Trial Register

Health condition

Pulmonary embolism
longembolie

Sponsors and support

Primary sponsor: University Medical Center
Source(s) of monetary or material Support: University Medical Center

Intervention

Outcome measures

Primary outcome

The diagnostic accuracy of the perfsuion scan criteria in comparison to CT scan.

Secondary outcome

1. Positive predictive value;

2. Negative predictive value;

3. Proportion of diagnostic Q scans.

Study description

Background summary

CT scanning has become a standard test in the diagnostic workup of patients with suspected PE. However, young patients, especially women, likely have an increased risk of (breast) cancer due to radiation exposure with CT scanning. Perfusion scanning has a much lower radiation exposure burden. Therefore, in this study, the accuracy of the PISAPED criteria for the evaluation of perfusion scans for the diagnosis of PE is studied in comparison to CT scan. Patients aged < or = 50 years old with suspected PE who need CT scanning according to current diagnostic work up criteria (i.e. either a 'likely' or 'high' clinical probability or an abnormal D-dimer test) will undergo perfusion scintigraphy. Q scan and CT scan will be compared for the absence or presence of PE.

Study objective

To study the accuracy of the PISAPED perfusion scan criteria compared with CT scanning in patients aged < or = 50 years with suspected pulmonary embolism, a likley or high clinical probability and/or an abnormal D-dimer.

Study design

Moment of diagnostic tests to rule out or confirm PE.

Intervention

Perfusion scintigraphy, chest X-ray and CT scan in patients with likely or high clinical probablity and/or an abnormal D-dimer with suspected pulmonary embolism.

Contacts

Public
Meibergdreef 9
P.W. Kamphuisen
Amsterdam 1105 AZ
The Netherlands
Scientific
Meibergdreef 9
P.W. Kamphuisen

Amsterdam 1105 AZ
The Netherlands

Eligibility criteria

Inclusion criteria

In- or outpatients aged < or = 50 years, with clinically suspected pulmonary embolism, who have a 'likely' (Wells score) or 'high' (revised Geneva score) clinical probability for pulmonary embolism and/or an abnormal D-dimer test and in hwom a cT scan will be made.

Exclusion criteria

1. Age <18 years or > 50 years;

2. Pregnancy;

3 (Low molecular weight) heparin for longer than 48 hours prior to eligibility assessment;

4. Inability to perfom a perfusion scan withing 24 hrs after CT scan;

5. Participation in a therapeutic study for pulmonary embolism is not an exclusion criterion.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-10-2008
Enrollment:	220
Type:	Anticipated

Ethics review

Positive opinion Date:	08-02-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2087
NTR-old	NTR2203
Other	MEC LUMC - substudy : P07.266
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A