Iodine Mapping using Subtraction in Pulmonary Embolism Computed Tomography versus Dual Energy Computed Tomography.

Published: 09-06-2016
Last updated: 17-04-2024

To evaluate image quality and accuracy of detection of perfusion defects associated with pulmonary pathology on iodine maps of the lung that are created by two different CT techniques: 1. A standard of care CTPA with DECT and 2. A new technique that...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pulmonary vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON43477

Source
ToetsingOnline

Brief title
InSPECT vs DECT

Condition

- Pulmonary vascular disorders
- Embolism and thrombosis

Synonym
Pulmonary embolism; Arteria pulmonalis embolism

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Industrie,Toshiba Medical Systems Corporation, 1385, Shimoishigami, Otawara-shi, Tochigi, 324-8550 Japan

Intervention

Keyword: DECT, embolism, subtraction, tomography

Outcome measures

Primary outcome

Main endpoint of the study is presence of perfusion as established by an expert panel with access to all imaging information (including CTPA, subtraction and DECT) and clinical follow-up. Accuracy of DECT and subtraction is established by observers who are blinded to CTPA and clinical data. Presence of iodine density differences in perfusion defects is measured using region of interest (ROI) measurements.

Images will be evaluated for objective and subjective image quality. Patient characteristics, radiation dose, clinical diagnosis, treatment decisions and patient outcome (all cause - and PE related mortality) will be recorded.

Secondary outcome

Not applicable.

Study description

Background summary

Pulmonary embolism (PE) is the third most common acute cardiovascular disease after myocardial infarction and stroke and is fatal in up to 30% of patients. Prompt diagnosis and treatment is critical and has been presumed to reduce mortality in up to 10%. Since 2007, multidetector CT pulmonary angiography

(CTPA) has been accepted as the reference standard for the diagnosis of acute PE. However, conventional pulmonary CTPA provides only morphologic information and does not allow functional assessment of the effects of thromboembolic clots on lung blood perfusion. Blood clots associated with pulmonary embolism cause abnormal blood flow with perfusion defects in a segmental or lobar distribution. Especially in case of small, peripheral pulmonary embolisms, it is these perfusion defects that are visible signs of pulmonary embolism. In conventional CTPA, enhancing pulmonary parenchyma cannot be distinguished from unenhancing tissue due to almost similar attenuation values. Color-coded maps of lung-attenuation tackle this problem to a little extent but are not able to visualize the contrast medium distribution selectively.

Dual energy CT does enable selective blood flow imaging by spectral defragmentation and generation of iodine maps. These iodine maps are able to demonstrate abnormalities that correspond to the histopathologic changes in acute and subacute pulmonary embolism. This increases sensitivity for detection of embolisms, in particular for small emboli at a subsegmental level or in more distal vessels. In addition, perfusion imaging might help in determining prognosis and therapy monitoring. Dual energy based perfusion imaging has therefore been successfully implemented in clinical practice as a complementary tool in detection of PE.

Study objective

To evaluate image quality and accuracy of detection of perfusion defects associated with pulmonary pathology on iodine maps of the lung that are created by two different CT techniques: 1. A standard of care CTPA with DECT and 2. A new technique that subtracts a low radiation dose unenhanced CT from mono-energetic CTPA (subtraction).

Study design

A total of 375 patients will undergo a standard CTPA with DECT according to local clinical guidelines. For the purposes of this study, patients will undergo an additional unenhanced, low-radiation dose chest CT. Standard reconstructions of all scans and DECT iodine maps will be obtained for clinical reporting and subsequent treatment decisions, according to standard clinical routine. For research purposes, selected mono-energetic images will be post-processed using a novel subtraction algorithm to create iodine maps of the lungs. The iodine maps based on the subtraction algorithm will not be used for clinical management, only the additional unenhanced scan will be used in clinical management.

Study burden and risks

CT imaging is associated with risks related to the use of radiation and

iodinated contrast administration. No additional contrast will be used as compared to standard clinical practice as patients will only undergo one CTPA scan. The CT protocol of this study has been carefully designed to have a radiation dose identical or even lower than standard CT protocols for pulmonary embolism detection. The estimated dose-length product (DLP) of standard CTPA with DECT in Meander Medical Centre is 167 mGy-cm (effective dose is 2.4 mSv, using 0,0146 mSv/mGy-cm as a conversion factor. We will expose patients who participate in the study to an estimated additional DLP of 72 mGy-cm due to the unenhanced scan, resulting in an additional estimated effective dose of 1,0 mSv. This implies that the total radiation dose is within the same range as radiation doses of other scans for PE detection in the Netherlands. The additional scan is not obligatory in pulmonary embolism diagnosis, but will be used for clinical evaluation of these patients.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- patients 35 years or older and able to provide informed consent
- clinically requested CTPA because of suspected pulmonary embolism
- available history and physical examination

Exclusion criteria

- pregnancy
- hemodynamic instability
- uncooperative patients
- contra-indication to intravenous iodine administration.
- inability to position the arms above the shoulders

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-07-2016
Enrollment:	375
Type:	Actual

Medical products/devices used

Generic name:	Siemens SOMATOM Definition Flash CT scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-06-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL56542.091.16

Study results

Results posted: 14-06-2016

First publication
01-01-1900