Fully Automated Scan Technique: Optimisation of Scan Timing in chest CT [FAST START trial]

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Primary objective:- To evaluate the performance of the FAST software in patients receiving a chest CT with regard to the number of non-diagnostic scans (> 300 HU) in comparison with standard care ('default' delay). Secondary objectives...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46707

Source
ToetsingOnline

Brief title
FAST START trial

Condition

- Other condition
- Respiratory tract neoplasms

Synonym
All lung pathologiees requiring chest CT

Health condition

pathologieen van de longen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Grant from Siemens Healthineers to department of radiology MUMC+ for multiple studies

Intervention

Keyword: Attenuation, Bolus Tracking Software, Chest CT, Scan Timing

Outcome measures

Primary outcome

Attenuation above 300 HU, as stated as diagnostic.

Secondary outcome

Timing, delay, objective image quality (attenuation, image noise, SNR and CNR),

subjective image quality (4-point Likert scale: 1=poor image quality;

2=sufficient image quality; 3=good image quality; 4=excellent image quality)

and CO (mL/min).

Study description

Background summary

Computed Tomography Angiography (CTA) is a non-invasive imaging tool widely used for various indications. Contrast media (CM) is used to enhance the intravascular lumen and organ parenchyma, depending on the indication. Recent technical advances in CT scan techniques allowed for a very fast scan acquisition with substantially increased image quality in terms of temporal and spatial resolution. These faster scan times account for a significant reduction in radiation dose, which is desirable in light of the *As Low As Reasonably Achievable* (ALARA) principle. Another advantage of the newer *high-end* scanners is the use of lower tube voltages, since many studies have shown that CM volumes can be reduced with usage of lower tube voltages.
However, with faster scan acquisition, challenges arise with regard to CM bolus timing. The risk of outrunning the CM bolus in these fast acquisitions is higher, subsequently leading to a decreased or even non-diagnostic enhancement (in Hounsfield Units (HU)). In addition, decreased CM volumes due to usage of

lower tube voltages also add to the risk of outrunning the bolus. When reducing the CM bolus, the injection time decreases and the window of peak enhancement is shorter and more narrow. Also, when injecting these smaller CM volumes at higher flow rates, although the peak enhancement is increased, the window of peak enhancement decreases more rapidly. Thus, when administered with the same flow rate, the peak of the enhancement curve will be lower, narrower and faster compared to larger CM volumes. This, in combination with the faster scan acquisition makes the timing of the start of the scan (scan start delay) highly important, since scanning at the peak enhancement is necessary to achieve a diagnostic image quality.
To determine scan delay, two techniques that are used frequently in daily clinical routine are the *bolus tracking* and *test bolus* technique. With the latter, a smaller CM bolus is administered before the actual scan, and the time to peak of the intravascular enhancement is determined with help of dedicated software (DynEva, Siemens Healthineers, Forchheim, Germany). When using the *bolus tracking* technique, no additional CM volume is administered. A region of interest (ROI) is placed in a large artery of interest (e.g. ascending or descending aorta), and a threshold enhancement is set prior to the scan (e.g. 100 HU). Repetitive low dose helical scans are acquired at the same level and the arrival of the CM bolus is followed. Once the threshold is reached, the scanner automatically starts the scan. Between reaching the threshold and the actual start of the scan, a manual post-tracking delay is set prior to scanning. This delay is necessary for both the table movement of the scanner to the starting point of the scan and the breath hold command. The problem is that this manual post-tracking delay is set prior to the scan, without information of the patient*s cardiovascular dynamics (e.g. cardiac output). Since cardiac output can vary greatly inter- and intra-patient, this fixed post-tracking delay may not be appropriate for all patients. Scanning with a sub-optimal post tracking delay could potentially result in suboptimal arterial enhancement and insufficient diagnostic quality.

With new bolus tracking auto-delay software (Fully Automated Scan Technique, FAST, Siemens Healthineers) the incidence of scans made at a suboptimal attenuation could be reduced. This software works the same as the *bolus tracking* technique, the difference is that the manual post-tracking delay is calculated automatically by the software7. During the low-dose helical scans at the level of the ROI, the attenuation in the ROI is used to predict the optimal enhancement curve. The software takes the injection protocol, tube voltage and patient parameters into account. A previously acquired database of numerous enhancement curves is consulted to predict this enhancement curve of the individual patient. The software then calculates the optimal post-tracking scan delay to scan at the peak enhancement. Thus, the optimal individual scan delay and enhancement, based on the patients physiology can be achieved, and the risk of non-diagnostic scans should decrease. Therefore, this study aims to evaluate the performance of the FAST software in patients receiving standard chest CT with regard to the number of non-diagnostic scans (< 300 HU) and compare this

with standard care (manual set pre-scan delay).

Study objective

Primary objective:
- To evaluate the performance of the FAST software in patients receiving a chest CT with regard to the number of non-diagnostic scans (> 300 HU) in comparison with standard care ('default' delay).

Secondary objectives:
- To assess the enhancement curses calculated by the FAST software with regards to scan timing and delay and compare it with the scan timing and delay of the control group ('default' delay)
- To assess the objective (intravascular attenuation, image noise, signal-to-noise ratio, and contrast-to-noise ratio) image quality parameters in patients receiving standard chest CT with the FAST software and compare it with the control group ('default' delay).
- To assess the subjective (Likert scale) image quality parameters in patients receiving standard chest CT with the FAST software and compare it with the control group ('default' delay).
- Calculation of CO with help of the testbolus attenuation curves.

Study design

This study is an observer blinded randomized controlled trial conducted according to Guidelines of GCP. This prospective study will assess the performance of the FAST software in patients receiving standard chest CT. We are aiming to prospectively enrol 316 consecutive patients, based on a sample size calculation (see 4.4; page 13), who will be referred for a chest CT. The inclusion period will be two years. Standard chest CT consists of an contrast-enhanced CT scan of the chest, performed with the bolus tracking technique. An additional test bolus will be added for quality assurance, no other changes will be made in the standard scan protocol. All patients who are referred for a standard chest CT will be eligible for inclusion. Patients will be enrolled in one of two groups, according to the software used. Group 1: FAST group, scanned with the new FAST software; Group 2: Control group, scanned with the a default delay set prior to scanning. No adjustments will be made in the standard scan settings used in daily practice, only scan delay will differ.

Intervention

NVT

Study burden and risks

The participants will receive a scan on referral from their clinician and the

scan will be performed according to normal clinical routine. Only patients already scheduled for clinically-mandated chest CT will be recruited. Scan protocol will not be altered for this research. Differences in intravascular attenuation may potentially impact the diagnostic accuracy of a chest CTA, especially when the attenuation is below a diagnostic level. However, since the scan delay calculated with the FAST software is more specific to patient physiology, it is not expected that the attenuation will be lower compared to the control group. Also, the FAST software has the possibility to manually start the scan in case the technician feels the delay is too long. This can be seen as an extra security measurement. An additional test bolus will be added to asure the quality of the software. Lastly, the CM protocol in this study is the standard injection protocol in our medical centre and is known to be sufficient for clinical purposes.

Participation in this study will not cause any delay in the standard CTA procedure. We therefore do not expect participation in this study to give any disadvantages for the subjects relative to the standard CTA protocol, which they would have undergone as part of their clinical care. The only trial-related burdens will be the randomization and additional low-dose low-volume test bolus.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients referrered for standard chest CT
Patients older than 18 and competent to give informed consent

Exclusion criteria

Hemodynamic instability;
Pregnancy;
Renal insufficiency (defined as Glomerular Filtration Rate (GFR) < 30 mL/min);
Iodine allergy;
Age under 18 years;
Absence of informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2018
Enrollment:	316
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-01-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL63106.068.17
Other	NL63106.068.17

Study results

Date completed:	31-12-2018
Actual enrolment:	223

Summary results
Trial ended prematurely