The relationship between contrast media volume and tube voltage in computed tomography of the liver, for optimal enhancement based on total body weight: A randomized controlled trial. [COMpLEx trial]

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON46148

Source
ToetsingOnline

Brief title
Body weight, CM volume and kV in liver CT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Hepatobiliary neoplasms malignant and unspecified
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
liver lesions; neoplasm

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Body Weight, Computed Tomography, Contrast Media, Tube Voltage

Outcome measures

Primary outcome

To evaluate the possibilities to reduce radiation dose and CM volume in patients receiving an abdominal CT scan. All scans performed in portal venous phase and with or without an unenhanced and/or arterial and/or delayed scan are included. A scan is defined diagnostic as an attenuation increase of >= 50 HU between the unenhanced and the portal venous phase scan is achieved. We hypothesise that in abdominal CT the tube voltage and therefore CM volume can be reduced with a sufficient liver enhancement of >= 50 HU.

Secondary outcome

To evaluate the objective IQ (liver attenuation [HU], image noise, SNR and CNR) in the various groups. SNR is calculated with the following formula:

Attenuation of the liver parenchyma

Standard deviation (SD) of the liver parenchyma attenuation

The CNR will be calculated accordingly:

Liver segment attenuation - Intramuscular

SD of the intramuscular attenuation

The subjective IQ in the four groups will be determined with the use of a 5-point Likert scale [1 = excellent; 2 = good; 3 = moderate; 4 = poor; 5 = very poor] (43).

The dose report form, as visible on our PACS workstation (IMPAX verse 6.6.1. 5003, AGFA HealthCare N.V., Mortsel, Belgium), will be used to subtract the radiation dose. The values for the portal venous phase scan of the total abdomen will be used to compare the radiation dose between scans.

Study description

Background summary

Computed Tomography (CT) is a non-invasive imaging tool, used for a great variety of indications. Contrast media (CM) is used to enhance vascular structures and organ parenchyma. The visibility of liver lesions depends mainly on the ratio between the size and the difference of the lesion to the background. A large lesion might be visible without administration of CM, whilst a smaller lesion needs the addition of CM to become visible. Additionally, CM can be useful in the characterisation of liver lesions. Heiken et al. (1995) found that an attenuation of the parenchyma after CM administration of at least * 50 Hounsfield units (HU) compared to an unenhanced scan (in the same patient) is necessary to recognize liver lesions. They

proposed a dosing factor of 0.521 g I/kg to be necessary to reach such attenuation at a tube voltage of 120 kV [1].
The parenchymal enhancement depends on patient, CT scanner and CM factors. Weight, height, cardiac output, age, gender, venous access, breath-holding, renal function and comorbidity all fall under patient factors [8]. Recently much research showed preferable outcomes for individualized CM injection protocols, in which the contrast bolus is adapted to patient TBW, LBW or body surface area (BSA) [6, 7, 9, 11-13]. In a recent feasibility study in our department, we evaluated the attenuation of the liver parenchyma. Results showed that a body weight adapted CM injection protocol resulted in more homogeneous liver enhancement compared to a fixed CM dose (not published yet).
With recent technological developments in X-ray tube technology it became possible to use lower tube voltages. As a result making it possible to perform scans with a sufficient image quality (IQ) and a low tube voltage and therefore a lower radiation dose [10]. Another advantage lies in the fact that reducing the tube voltage, approaching 33 keV k-edge of iodine, results in an increase in attenuation of the iodine. The new technological developments make it possible to reduce the radiation dose and CM volume at the same time.
As recommended by the supplier, it is possible to calculate the total iodine load (TIL) that can be spared with the use of lower kV settings [14]. A reduction of 10 kV should result in a 10% reduction in CM volume. Reducing the tube voltage from 120 to 90 kV should therefore lead to a 30% reduction in CM volume. As mentioned before it is preferred to use an individualized CM injection protocol based on TBW or LBW. For this study, we have adapted this theory to the concept of TBW. Table 1. below indicates which dosing factors should be used for each kV setting, based on the recommendations mentioned in the above.

Study objective

The aim of present study is to investigate if adapting the dosing factor based on TBW and therefore the CM volume to the tube voltage used, results in a more homogeneous liver enhancement. We hope to find a more homogeneous enhancement between patients and in the same patient, regardless of body composition and tube voltage used.

Study design

This study is a randomized controlled trial conducted according to Guidelines of GCP. This prospective study will assess the liver enhancement with regard to TBW adapted individualized injection protocols and kV setting.
We are aiming to prospectively enrol 64 patients in each arm. The inclusion period will be two years. All patients referred for an abdominal or liver CT scan, with or without a chest CT, will be eligible for inclusion. Technicians will schedule patients on the 3rd generation DSCT (SOMATOM Force, Siemens Healthineers) depending on clinical program and logistics. The patient will be

scheduled in one of four arms (figure 1):
1. CM injection protocol with a dosing factor of 0.521 grams of Iodine per kg of TBW and a tube voltage of 120 kV.
2. CM injection protocol with a dosing factor of 0.521 grams of Iodine per kg of TBW and a tube voltage of 90 kV.
3. CM injection protocol with a dosing factor of 0.417 grams of Iodine per kg of TBW and a tube voltage of 100 kV.
4. CM injection protocol with a dosing factor of 0.365 grams of Iodine per kg of TBW and a tube voltage of 90 kV.
All patients scheduled for a CT scan, which includes a portal venous phase abdominal scan, will be included. In case an unenhanced CT is not part of the scan protocol, one unenhanced slice at the level of the portal vein will be added to the protocol before administration of CM.

Intervention

NVT

Study burden and risks

The participants will receive a scan based on referral from their clinician and the scan will be performed according to normal clinical routine. Only patients already scheduled for clinically mandated abdominal CT will be recruited. A very small extra amount of radiation dose will be given to the patient, in order to acquire a single, unenhanced CT slice of the liver. Differences in attenuation, because various tube voltages and CM volumes are used, may potentially impact the diagnostic accuracy of the abdominal CT, especially when the attenuation is below a diagnostic level. However, since the CM volume is adapted to the lower tube voltages and these lower kV settings and CM volumes are already described in different papers with sufficient diagnostic IQ, it is expected that the attenuation will be sufficient. Also, CareDose 4DTM is used to guarantee an IQ as specified by the supplier.
Participation in this study will not cause any delay in the standard CT procedure. We therefore do not expect participation in this study to give any disadvantages for the subjects relative to the standard CT protocol, which they would have undergone as part of their clinical care.

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 referred for abdominal CT
Patients older than 18 years and competent to sign an informed consent

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2018
Enrollment:	256
Type:	Actual

Ethics review

Approved WMO

Date:	29-11-2018
Application type:	First submission
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	NL66971.068.18
Other	NL66971.068.18

Study results

Date completed:	26-06-2019
Actual enrolment:	256