A feasibility study comparing two strategies of oral contrast in patients undergoing contrast-enhanced abdominal CT: 50 ml Télébrix Gastro + 950 ml water vs 1000 ml water only.

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The aim of this study is to compare the image quality, diagnostic confidence and patient discomfort when using either positive (50 ml Télébrix Gastro + 950 ml water) or negative 1000 ml water only in outpatients undergoing a contrast-enhanced...

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

Summary

ID

NL-OMON44229

Source
ToetsingOnline

Brief title
Oral contrast agents in patients undergoing contrast-enhanced abdominal CT.

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Hepatic and hepatobiliary disorders
- Gastrointestinal neoplasms malignant and unspecified

Synonym
not applicable

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Abdomen, Computed Tomography, Enteric contrast agent

Outcome measures

Primary outcome

Primary parameters: quality of the scans and the diagnostic confidence by the

radiologist.

Secondary outcome

Secondary parameters: patients discomfort and radiation exposure.

Study description

Background summary

Although CT protocols vary by institution, equipment, setting and clinical question, the default protocol in our practice for outpatient contrast-enhanced abdominal CT scans includes both oral contrast including Télébrix Gastro (so called positive oral contrast) and IV contrast administration. The justification for oral contrast for emergency department patients has been questioned and extensively studied leading to withholding any oral contrast. The advantages of withholding oral contrast in the emergency department may be translated to routine intravenously enhanced CT of the abdomen in the outpatient setting. However there are no data on withholding of oral contrast in this patient population. In different studies, however the positive oral contrast has been replaced by water only, so called **negative oral contrast*. The routine use of positive contrast in the outpatient setting has multiple direct and indirect effects, including increased cost, decreased practice efficiency, patient inconvenience and discomfort and higher radiation exposure.

Study objective

The aim of this study is to compare the image quality, diagnostic confidence and patient discomfort when using either positive (50 ml Télébrix Gastro + 950 ml water) or negative 1000 ml water only in outpatients undergoing a contrast-enhanced abdominal CT scans.

Study design

A single-centre study including 200 patients (100 in each arm). Patients will be randomised by a four block randomisation procedure.
Patient will receive either negative oral contrast (1000 ml water) or positive oral contrast (50 ml Télébrix Gastro + 950 ml water).

Study burden and risks

BURDEN:
1) Patients will be allocated to one of the arms.
2) Patients will be asked to complete a questionnaire.

RISKS ASSOCIATED WITH PARTICIPATION
We do not expect any risk associated with oral water administration.

LONG AND SHORT TERM BENEFITS
There are no benefits for participants. In the future replacing positive contrast by negative contrast agent, will lead to cost savings (direct and indirect), better patients acceptance and presumable lower radiation exposure.

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 scheduled to undergo an abdominal CT with oral contrast at the department of Radiology;
Outpatients;
> 18 years.

Exclusion criteria

Patients undergoing CT for other research purpose;
Patients who are not willing to participate;
Not able to understand and/or give written informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-12-2017
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	28-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL63168.018.17