Multi-center, randomized comparison study to eVALUatE outcomes and resource needs of imaging and treatment following Primovist-enhanced MRI of the liver in comparison to extracellular contrast media (ECCM)-enhanced MRI and contrast-enhanced computed tomography (CT) in patients with a history of colorectal cancer and known or suspected metachronous liver metastases

Published: 27-10-2008
Last updated: 06-05-2024

The main objective of this study is to evaluate outcomes and resource needs of imaging and treatment following Primovist-enhanced MRI (PV-MRI) as com¬pared to ECCM-enhanced MRI (ECCM-MRI) and contrast-enhanced CT (CE-CT) in patients with a history…

Ethical review	Not approved
Status	Will not start
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON33542

Source
ToetsingOnline

Brief title
Primovist VALUE study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
metachronous liver metastases, metastasis in the liver after colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: evaluate, livermetastases, MRI + CT, outcome/resources

Outcome measures

Primary outcome

Proportion of patients for whom further imaging is required to come to a

therapy decision after initial imaging of the liver with either PV-MRI,

ECCM-MRI or CE-CT.

The null hypothesis of the test for the primary efficacy variable with regard

to this proportion using PV-MRI (i.e. PPV-MRI) H0: PPV-MRI * PComparator

will be tested against the alternative hypothesis H1: PPV-MRI <

PComparator using the exact Fisher test.

The one-sided significance level will be set to 0.025. There will be three

tests:

1. Using as comparator the pooled data from ECCM- MRI and CE-CT.

2. Using as comparator the data from CE-CT.

3. Using as comparator the data from ECCM- MRI.

After examination of at least 100 patients in each study group, one interim analysis will take place to adjust the sample size. Fisher*s combination test will be used according to Bauer, Kieser, and Lehmacher, 1999.

Secondary outcome

Another objective of this study is to assess safety of PV-MRI as compared to ECCM-MRI and CE-CT in patients with known or suspected liver metastases based on the evaluation of adverse events.

Study description

Background summary

In patients with a history of colorectal cancer, i.e. cancer that starts in the colon or rectum, liver metastases develop in 40 % to 50 % of patients in the first three years after the surgical resection. High precision in detecting, localizing, and characterizing such liver lesions is important, because the treatment decision may have consequences for the prognosis of both life expectancy and quality of life. Surgical resection of colorectal liver metastases is the only potentially curative method and dramatically improves prognosis. Therefore, the timely and correct diagnosis and the determination of resectability are of utmost importance and the key question for diagnostic imaging procedures of the liver in patients.

Study objective

The main objective of this study is to evaluate outcomes and resource needs of imaging and treatment following Primovist-enhanced MRI (PV-MRI) as com¬pared to ECCM-enhanced MRI (ECCM-MRI) and contrast-enhanced CT (CE-CT) in patients with a history of colorectal cancer and known or suspected metachronous liver metastases based on the evalua¬tion of the following:
* Proportion of patients for whom further imaging is required to come to a therapy decision after initial imaging of the liver with either PV-MRI, ECCM-MRI or CE-CT (primary efficacy variable)
* Proportion of patients with intra-operatively modified surgical plans based on either PV-MRI, ECCM-MRI or CE-CT
* Diagnostic performance of either PV-MRI, ECCM-MRI or CE-CT in comparison to

final diagnosis
* Confidence in diagnosis and therapeutic decision
* Resource needs for imaging and treatment after either PV-MRI, ECCM-MRI or CE-CT
Another objective of this study is to assess safety of PV-MRI as compared to ECCM-MRI and CE-CT in patients with known or suspected liver metastases based on the evaluation adverse events.

Study design

Multi-center, randomized phase IV inter-individual (parallel-group) comparison study.
Patients will be randomized to either undergo PV-MRI, ECCM-MRI or CE-CT. Efficacy and safety assessments will be carried out on-site by the clinical investigators after the imaging procedure. To determine the proportion of patients for whom further imaging is required after initial imaging of the liver, a consensus decision by the treating radiologist and surgeon will be obtained.
To determine the proportion of patients with intra-operatively modified surgical plans following initial surgical planning on the basis of the imaging procedure(s) all available documentation on the surgical procedure and its outcome will be collected.

Intervention

patients will be randomized in 3 groups during the first imaging procedure of the liver: PV-MRI, ECCM-MRI or CE-CT.
In case further imaging is necessary, 1 of the 2 remaining imaging procedures should be chosen to be performed (the procedure/contrast agent that is used during the first procedure will be excluded in the second procedure).

Study burden and risks

The possibility exist that subjects will be asked to visit the clinic for a second imaging procedure, to perform the imaging procedure that could have been the first choice of the investigator in case the subject did not participate in the trial.

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

1.Patients with known or suspected metachronous liver metastases secondary to colorectal cancer who are scheduled for further contrast-enhanced tomographic imaging
2.Patients willing to undergo the study procedures
3.Patients who are fully informed about the study and have signed the informed consent form

Exclusion criteria

1.Patients (men or women) under 18 years of age
2.Patients who have previously entered this study
3.Patients who have received any contrast material within 24 hours before injection of study drug, or who are scheduled to receive any contrast material within 24 hours after injection
4.Patients who have received or will receive any investigational drug 48 hours before injection of the study drug or during study participation
5.Women who are pregnant, lactating or who are of childbearing potential and have not had a negative urine pregnancy test at baseline visit(s)
6.Patients not eligible to contrast media (CM) injection according to product labeling
7.Patients scheduled for liver-specific MRI other than Primovist-enhanced MRI, e.g. Multihance-, Teslascan- or SPIO-enhanced MRI

8.Patients who require emergency treatment
9.Patients who are clinically unstable and whose clinical course is unpredictable (e.g. due to previous surgery, acute myocardial infarction)
10.Patients with any physical or mental status that interferes with the signing of informed consent
11.Patients with known anaphylactoid or anaphylactic reaction to any contrast media or hypersensitivity to any allergen including drugs
12.Patients with a contraindication for MRI or CT.
13.Patients with severe renal impairment (eGFR value of < 30 ml/min/1.73m2).
14.Close affiliation with the investigational site; e.g., a relative of the investigator, dependent person (e.g., employee or student of the investigational site)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-10-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Not approved

Date:	21-04-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2008-000583-16-NL
CCMO	NL24142.041.08