A phase 1, placebo-controlled, ascending-dose study to assess the safety and imaging characteristics of GE-137 Injection in healthy volunteers, and to assess its safety and imaging characteristics in subjects with high suspicion of colorectal cancer

Published: 02-06-2010
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The study the safety and imaging characteristics of GE-137

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON36432

Source
ToetsingOnline

Brief title
GE-137-001

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Colorectal cancer

Research involving

Human

Sponsors and support

Primary sponsor: GE Healthcare
Source(s) of monetary or material Support: GE Healthcare

Intervention

Keyword: Colorectal cancer, GE-137 injection, imaging safety assessment, placebo-controlled

Outcome measures

Primary outcome

Safety of GE-137 in healthy volunteers and patients with high suspicion of

colorectal cancer, using standard safety measures

Secondary outcome

-To detemine the optimal dose of GE-137 and the optimal timing between GE-137

dosing and endoscopy.

-To determine if GE-137 detects areas of increase fluorescence in the colon

that correlate with pathology and c-Met expression in patients with high

suspicion of CRC

Study description

Background summary

Colorectal cancer is 1 of the major causes of cancer deaths globally. The clear link between risk factors like age and predisposition makes Colorectal cancer (CRC) an ideal candidate for screening. Stratification of benign v.s. adenomatous laesion is not readily possible with routine (with light) colonoscopy. Also, light colonoscopy is less sensitive for the detection of flat laesions. GE Healthcare has developed a fluorescent marker ((GE-137) for potential diagnosis for CRC.
GE-137 targets C-met, which is a marker for CRC. With GE-137 and red light

colonoscopy, early leasions may be detected.

Study objective

The study the safety and imaging characteristics of GE-137

Study design

Het study consists of two parts.
Firstly, in healthy volunteers the safety and optimal dosing of GE-137 will be investigated. Secondly, the safety and imaging characteristics of GE-137 will be investigated in patients with high suspicion of colorectal cancer.
The first part (in healthy volunteers) is a randomised, placebo controlled, parallel single rising dose study (4 dose groups GE-137 from 0.02 to a maximum of 0.36 mg/kg body weight [bw]).
The second part is an open-label study with one dose of of GE-137.

Intervention

GE-137 or placebo

Study burden and risks

At sceening clinical signifcant abnormalities might be discovered. The endoscopy has a slight change (smaller than 1%) for a complication (bowel perforation of bleeding of intestine).
A day before the endoscopy, the subjects need to have a bowel preparation (drinking 2L of Movi prep (healthy volunteers and patients) and 2 tablets of bisacodyl (patients only)).

Contacts

Public
GE Healthcare

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy volunteers:
(1) The subject is >=18 and <=70 years old at screening.
(2) Female subjects need to be either surgically sterile, post menopausal or pre menopausal with a negative urine pregnancy test.
(3) The subject is able and willing to comply with study procedures, and signed and dated informed consent is obtained before any study-related procedure is performed.
(4)The subject has a normal or clinically acceptable medical history, physical examination, and vital signs findings at screening
(5)The subject*s screening ECG and clinical laboratory test results are within normal limits.
(6)The subject has negative test results for drug and alcohol screening.
(7)The subject*s body mass index is <= 30 but not <18 kg/m2.
(8)The subject has negative test results for hepatitis B, hepatitis C, and human immunodeficiency virus.;Subjects with High Suspicion of Colorectal Cancer
(1) The subject is >= 45 years old at screening.
(2) Female subjects need to be either surgically sterile, post menopausal, or pre menopausal with a negative urine pregnancy test
(3) The subject has high suspicion of CRC.
(4) The subject is able and willing to comply with study procedures, and signed and dated informed consent is obtained before any study-related procedure is performed.
(5) The subject has a normal or clinically acceptable medical history, physical examination, and vital signs findings at screening .
(6)The subject*s screening ECG and clinical laboratory tests are within normal limits.
(7)The subject*s body mass index is <=30 but not <18 kg/m2.

Exclusion criteria

Healthy Volunteers

(1) If female, the subject is lactating or pregnant.
(2) The subject has been previously included in this study.
(3) Treatment with another investigational medicinal product (IMP) within 3 months prior to screening or more than 4 times in the past year.
(4) Loss of blood outside the limits of Sanquin within 3 months prior to screening.
(5) The subject has received any prescription or non-prescription medication regularly between 14 days and 1 day prior to IMP administration. Occasional use of analgesics, such as ibuprofen and paracetamol, etc., is permitted at the discretion of the investigator. Use of hormonal contraceptives is also permitted. ;Subjects with High Suspicion of Colorectal Cancer
(1) If female, the subject is lactating or pregnant.
(2) The subject is being treated or has been treated with chemotherapy or radiation within the 3 months before enrolment.
(3) A biopsy has been obtained from the colon within the 3 weeks before enrolment.
(4) The subject has been previously included in this study.
(5) Treatment with another IMP within 3 months prior to screening or more than 4 times in the past year.
(6) Loss of blood outside the limits of Sanquin within 3 months prior to screening.
(7) The subject has had any significant change in their regular prescription or non-prescription medication between 14 days and 1 day prior to IMP administration. Occasional use of analgesics, such as ibuprofen and paracetamol, etc., is permitted at the discretion of the investigator. Use of hormonal contraceptives is also permitted.
(8) The subject has a history of alcohol and/or drug abuse within the previous 12 months, based on a review

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2010
Enrollment:	35

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oncology diagnostic
Generic name:	GE-137 Injection

Ethics review

Approved WMO Date:	02-06-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-07-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-08-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-08-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-10-2010

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	09-12-2010
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	16-01-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-01-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	EUCTR2010-019197-33-NL
CCMO	NL32320.058.10