A Phase IIb, Open Label Study for the Detection of Dysplastic Colorectal Polyps during Colonoscopy after EMI-137 Injection in Patients with High Suspicion of Colorectal Cancer.

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Primary ObjectivesTo assess the efficacy of 0.13mg/kg EMI-137 IV injection to detect lesions during colonoscopy, in subjects at high suspicion of developing colorectal cancer by:- Comparing the number of pathological lesions detected with WL with...

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

Summary

ID

NL-OMON47367

Source
ToetsingOnline

Brief title
EMI-137 for detection of dysplastic colorectal polyps

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
bowel polyps, dysplastic colorectal polyps

Research involving
Human

Sponsors and support

Primary sponsor: Edinburgh Molecular Imaging Ltd.
Source(s) of monetary or material Support: Edinburgh Molecular Imaging Ltd.

Intervention

Keyword: Detection, Dysplastic colorectal polyps, EMI-137

Outcome measures

Primary outcome

- Detection of additional pathological lesions using WL+ FL compared to WL only

- Fluorescence signal of lesions

- TBR signal, defined as fluorescent signal of the lesion compared to

fluorescence signal

of tissue surrounding the lesion

- Concordance of fluorescence intensity and lesions with different pathological

lesion statuses and C-Met expression.

Secondary outcome

Safety and tolerability endpoints

- Treatment-emergent (serious) adverse events ((S)AEs).

- Concomitant medication

- Clinical laboratory tests

o Haematology

o Chemistry

o Urinalysis

- Vital signs

o Pulse Rate (bpm)

o Systolic blood pressure (mmHg)

o Diastolic blood pressure (mmHg)

o Body temperature (*C)

- Presence of injection site reactions

Pharmacokinetic endpoints

Pharmacokinetics will be assessed by a single, in vivo, spectroscopy derived, quantitative measurement of the lesion (target) and normal bowel tissue (background). These parameters will later be converted to a target to background ratio.

Study description

Background summary

Colorectal cancer (CRC) is a major cause of cancer death, and colonoscopy is firmly established as the mainstay of CRC prevention and detection. Technical aspects of endoscopic imaging have a major role in determining polyp detection rates. Imaging at colonoscopy is currently performed using white light (WL), which is not optimal for detection of smaller and non-polypoid lesions, leading to miss rates of up to 25%. Optical imaging, using agents that targets (pre)malignant lesions coupled to a fluorescent dye, could improve polyp detection during colonoscopy.

Study objective

Primary Objectives
To assess the efficacy of 0.13mg/kg EMI-137 IV injection to detect lesions during colonoscopy, in subjects at high suspicion of developing colorectal cancer by:
- Comparing the number of pathological lesions detected with WL with the number of lesions detected with WL+FL
- Investigating the concordance of fluorescence intensity and histologic status.
- Establishing target to background ratio (TBR) of fluorescent lesions.
Secondary Objectives

- To assess the safety and tolerability of 0.13mg/kg EMI-137 iv injection;
- To assess the practical application of the technique, e.g.
o Ease of use of the fluorescence colonoscopy
o Ease of use of EMI-137 for injection;
- To assess the tissue pharmacokinetics of a single IV injection of 0.13mg/kg EMI-137 by in vivo quantification of fluorescence signals in polyps and normal tissue by spectroscopy using 2 colonoscopes;
- To assess the optimal time window between dose administration and fluorescence imaging (stage 1);
- To assess c-MET expression and fluorescence on fluorescence microscopy in biopsied lesions.

Study design

Open-label, single dose, phase IIb, multicenter study in patients with a suspicion of colorectal cancer undergoing colonoscopy. Colonoscopy will be performed using white light (WL) and fluorescence light (FL) with the order in which WL or WL/FL will be randomized per subject.

Intervention

fluorescence guided colonoscopy after EMI-137 administration.

Study burden and risks

The risks of participation for the patients in the trial include hypersensitivity reactions and an increased risk of bowel perforation. These risks are deemed minimal. Nevertheless precautionary measures (supervised administration by qualified staff and availability of medical treatment to treat hypersensitivity reactions) are in place and these effects are generally well manageable. The extra burden of the trial is minimal, the research will for the largest part coincide with routine care and the proposed procedures. We therefore believe this research that, could possibly provide a useful tool to find (more) malignant lesions and possibly improves patient outcome, is justified.

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. Signed informed consent prior to any study-mandated procedure;
2. Healthy male or female subjects aged 18 years or older;
3. Female subjects need to be either surgically sterile (has had a documented bilateral oophorectomy and/or documented hysterectomy), post-menopausal (cessation of menses for more than 1 year), or pre-menopausal with a negative urine pregnancy test performed at screening and a negative urine pregnancy test performed within 24 hours of administration of EMI-137 Injection. Pre-menopausal female subjects should also employ an effective method of birth control up to 90 days after EMI-137 administration. Barrier contraceptives must be used throughout the study in both sexes.
4. The subject has a positive FOB test or clinical suspicion on colorectal cancer and is scheduled to undergo a colonoscopy.
5. The subject has a normal or clinically acceptable medical history, physical examination, and vital signs findings at screening (within 35 days prior to administration of study drug).
6. The subject*s screening ECG and clinical laboratory tests are within normal limits, or if any are outside of normal limits they are considered to be clinically insignificant.

Exclusion criteria

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 or another fluorescence IMP.
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 EMI-137 administration.
8. The subject has a history of alcohol and/or drug abuse within the previous 12 months.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	EMI-137
Generic name:	n.a.

Ethics review

Approved WMO

Date:	26-10-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-12-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-04-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-04-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-08-2017
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-03-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2016-002827-27-NL
CCMO	NL58475.056.16