Study of tolerability, biodistribution and dosimetry of Technetium-99m radiolabelled Fucoidan

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To evaluate the tolerability (adverse effects) of 99mTc-Fucoidan in 10 healthy volunteers (phase I).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON46586

Source
ToetsingOnline

Brief title
NANOATHERO

Condition

- Embolism and thrombosis

Synonym
healthy volunteers in this study; in the future cardiovasular disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: EU

Intervention

Keyword: atherothrombosis, cardiovascular disease, Fucoidan, P-selectin

Outcome measures

Primary outcome

The primary endpoint is tolerability based on the following: adverse events,

vital signs, clinical examination, ECG, clinical laboratory measurements.

Secondary outcome

The secondary objectives are to determine:

1. Biodistribution (blood clearance, tissue distribution)

2. Dosimetry (effective dose [in mSv] per organ and per individual determined

from biodistribution).

Study description

Background summary

The development of an innovative imaging agent capable of non-invasively detecting vulnerable plaques is a major goal of research in cardiovascular pathology. Such a tool would allow better identification of patients at risk for acute cardiovascular events. We have shown that 99mTechnetium-labeled (99mTc) Fucoidan can target P-selectin expressed by in vitro activated human platelets and in vivo in an animal model of aortic thrombosis as well as endocarditis. One of the objectives of the Nanoathero program is the clinical translation of 99mTc-Fucoidan scintigraphy. First, we will study the tolerability and the dosimetric evaluation of this new radiopharmaceutical in humans.

Study objective

To evaluate the tolerability (adverse effects) of 99mTc-Fucoidan in 10 healthy volunteers (phase I).

Study design

A single-center, interventional, open, nonrandomized, safety assessment (phase I) of a new diagnostic imaging technique in 10 healthy volunteers.

Study burden and risks

The development of an innovative imaging agent capable of non-invasively detecting vulnerable plaques is a major objective of research in cardiovascular pathology. Such a tool would improve identification of high-risk patients, allowing for initation or intensification of treatment.
In the present study, participating subjects receive no direct or immediate benefits. The burden and risk of participating in this study is estimated to be low. Patients will visit the clinical trial unit 3 times, with an estimated total duration of 10 hours. A total of 87 ml of blood will be drawn. There are no direct toxic effects associated with the administration of 99mTc-Fucoidan, except for the risks inherent to radiation exposure. The maximum exposure in this study is 2.5 mSv. As a phase I, tolerability, biodistribution and dosimetry study, this trial involves healthy volunteers.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Adult subjects of either gender, aged 18 years or older
- BMI between 18 and 35 kg/m2
- Effective contraception in women of childbearing age
- Use of effective contraception in men for 24 hours after injection of 99mTc-Fucoidan

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Progressive and chronic disease
- Chronic infection with HIV, HBV or HCV
- Clinically significant abnormalities during screening
- Pregnancy or breast-feeding
- Active medication use or previous long-term intake of medication
- Any other treatment that could interfere with the conduct or interpretation of the study in the opinion of the investigator
- Any other clinically relevant condition that could interfere with the conduct of the study in the opinion of the investigator
- Standard contra-indications to SPECT/CT
- Inability or unwilling to comply with protocol requirements, or deemed by the investigator to have a disorder that may compromise the ability to give informed

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2018
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	99mTc-Fucoidan
Generic name:	Technetium-99m radiolabelled Fucoidan

Ethics review

Approved WMO Date:	08-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-07-2018
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
EudraCT	EUCTR2017-001015-36-NL
ClinicalTrials.gov	NCTisaangevraagd
CCMO	NL64194.018.17

Study results

Date completed:	23-10-2018
Actual enrolment:	10