A proof-of-concept study to evaluate 99mTechnetium radiolabelled Fucoidan as diagnostic modality for thrombosis

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To determine the uptake of 99mTc-Fucoidan in a fresh thrombus of patients with acute deep vein thrombosis (DVT).

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

Summary

ID

NL-OMON47990

Source
ToetsingOnline

Brief title
Fucoidan-DVT

Condition

- Embolism and thrombosis

Synonym
patients with a blood clot in one of the legs, patients with deep venous thrombosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Deep vein thrombosis, Fucoidan, P-selectin

Outcome measures

Primary outcome

To assess the difference in uptake of 99mTc-Fucoidan in the affected vein

versus the corresponding vein in the unaffected leg of patients with acute DVT.

Secondary outcome

To assess the effect of of Fucoidan on monocyte-endothelial and

monocyte-platelet interaction in stimulated endothelium ex vivo

Study description

Background summary

The development of an innovative imaging agent capable of non-invasively detecting fresh thrombus formation would greatly aid in the diagnosis and risk stratification of a large spectrum of different diseases, amongst which are recurrent deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke. Furthermore, as our imaging target P-selectin is upregulated in activated endothelium, this imaging agent will likely be able to identify vulnerable plaques. Additionally, this imaging technique is likely to be able to distinguish fresh from old thrombus, thereby allowing us to distinguish between a recurrence of deep vein thrombosis and post-thrombotic syndrome. Hereby we can prevent unnecessary lifelong anticoagulant treatment.

Study objective

To determine the uptake of 99mTc-Fucoidan in a fresh thrombus of patients with acute deep vein thrombosis (DVT).

Study design

A single-center, interventional, open, non-randomized, diagnostic assessment (phase IIa) of a new imaging agent in 12 patients with acute DVT.

Study burden and risks

The results of this study contribute to the development of a novel imaging biomarker in a very large spectrum of thrombotic diseases. For cardiovascular diseases, this may allow for better identification of high-risk patients and might be more specific than conventional diagnostic methods in patients with a cardiovascular event. In the case of DVT, this imaging technique could potentially differentiate between acute and chronic events, thereby preventing unnecessary treatment. As the current study is a phase IIa study, subjects receive no direct or immediate benefits. There are no direct toxic effects associated with the administration of 99mTc-Fucoidan, except for the limited risks inherent to radiation exposure.

Note that all included subjects have experienced a first episode of DVT, and 1 out of 5 patients will experience a recurrence in the first 5 years. In case this tracer (99mTc-Fucoidan) effectively detects fresh thrombus, the patients themselves may benefit in the future from the correct diagnosis of recurrent DVT versus post-thrombotic syndrome, possibly preventing unnecessary lifelong treatment. Therefore, the subjects fall into risk category IIb, according to the *Human exposure to ionising radiation for clinical and research purposes* guidelines of the Netherlands Commission on Radiation Dosimetry (CCMO website).

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

- Adult subjects of either gender, aged 50 years or older, with a compression ultra-sound demonstrated acute DVT, < 24 hours after treatment initiation
- BMI between 18 and 35 kg/m2

Exclusion criteria

- Standard contra-indications to SPECT
- Any medical condition or treatment that could interfere with the conduct of the study in the opinion of the investigator
- 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 consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-11-2019
Enrollment:	12
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	26-04-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2021
Application type:	Amendment
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	EUCTR2019-000133-39-NL
CCMO	NL68750.018.19