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

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24363

Source
NTR

Brief title
NANOATHERO

Health condition

Fucoidan; P-selectin; cardiovascular disease; atherosclerosis; thrombosis

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: EU FP7

Intervention

Outcome measures

Primary outcome

Tolerability will be evaluated on the frequency and severity of adverse events, as well as on the following parameters:

- Vital signs

- Physical examination

- ECG

- Clinical blood laboratory measurements

Secondary outcome

- Biodistribution (blood clearance and tissue biodistribution)

- 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

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 design

After injection of 99mTc-Fucoidan, t=30min, 1.5h, 3h, 6h, 24h and 7d

Intervention

99mTc-Fucoidan SPECT/CT

Contacts

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Eligibility criteria

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:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2018
Enrollment:	10
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6703
NTR-old	NTR6873
Other	METC AMC Amsterdam : 2017_321

Study results