Arterial wall inflammation measured with 18F-FDG PET/CT in patients with statin intolerance before and after treatment with a PCSK-9 inhibitor

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20315

Source
Nationaal Trial Register

Brief title
VISTA

Health condition

Cardiovascular risk
Statin intolerance

Sponsors and support

Primary sponsor: University of Amsterdam
Source(s) of monetary or material Support: This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 667837.
Investigator initiated research, support from Regeneron.

Intervention

Outcome measures

Primary outcome

The primary endpoint is the change in 18F-FDG target to background ratio (TBR) following 12 weeks of PCSK-9 inhibition

Secondary outcome

The secondary endpoints are the difference in inflammatory parameters before and after PCSK-9 inhibition and to evaluate whether there is a correlation between 18F-FDG PET activity in arterial wall and circulating inflammatory markers

Study description

Background summary

This is a multi-center, double-blind, placebo-controlled, intervention study in 50 subjects using PCSK9 inhibition in patients with increased CV-risk and statin intolerance. The primary endpoint is the change in 18F-FDG target-to-background ratio (TBR) following 12 weeks of treatment.

Study objective

To assess the change in arterial wall inflammation, measured with 18F-FDG PET/CT, in patients
with increased CV-risk and statin intolerance due to statin-associated muscle symptoms after PCSK9 inhibition

Study design

Two weekly treatment for 12 weeks

Intervention

Placebo or Alirocumab 150 mg s.c. once every two weeks

Contacts

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Eligibility criteria

Inclusion criteria

Increased CV-risk

Aged 50 years and older

Statin-associated muscle symptoms for at least 3 different statins

LDL-C > 100 mg/dL

Exclusion criteria

Major exclusion criteria:

CV-event in last 3 months

Diabetes Mellitus

Systemic auto-immune disease

Cancer

Study design

Design

Study type:	Interventional
Intervention model:	Factorial
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-05-2017
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-12-2017
Application type:	First submission

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	NL6650
NTR-old	NTR6884
Other	METC AMC : 2016_321

Study results