Postprandial effects of alirocumab on lipemia and inflammtion

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22535

Source
Nationaal Trial Register

Brief title
PLEIADES-pcsk9

Health condition

Diabetes Mellitus Type 2 (T2DM), postprandial lipemia

Sponsors and support

Primary sponsor: Franciscus Gasthuis
Source(s) of monetary or material Support: Regeneron

Intervention

Outcome measures

Primary outcome

Primary endpoint is effect of alirocumab on postprandial leukocyte activation markers (CD11b, CD66b and CD35).

Secondary outcome

Secondary endponts are the effect of 9 weeks of treatment with alirocumab on postprandial lipemia (apoB48, triglycerides, free fatty acids and b-hydroxybutyrate), oxidative stress (myeloperoxidase) and vascular function (arterial pulse wave velocity and arterial pulse wave analysis).

Study description

Background summary

Few studies have proven to be efficient in reducing cardiovascular risk in diabetes. Recently, treatment of patients at high cardiovascular risk with a pcks9-inhibito has proven to both significantly reduce LDL-cholesterol and cardiovascular risk. We aimed to explore the postprandial effects of alirocumab both on lipids and inflammation in male subjects with type 2 diabetes on intensive insulin treatment.

Study objective

Treatment with alirocumab will reduce postprandial hyperlipidemia and thus reduce postprandial leukocyte activation, diminish the generation of postprandial oxidative stress and improve postprandial vascular dysfunction in men with type 2 diabetes mellitus

Study design

0 and 12 weeks

Intervention

9 weeks treatment with either biweekly alirocumab 150 mg or bikweeekly matching placebo.

Before and after treatment oral fat loading test (OFLT).

Contacts

Public
Franciscus Gasthuis, Department of Internal Medicine

Benjamin Burggraaf
Kleiweg 500

Rotterdam 3045 PM
The Netherlands

Scientific
Franciscus Gasthuis, Department of Internal Medicine

Benjamin Burggraaf
Kleiweg 500

Rotterdam 3045 PM
The Netherlands

Eligibility criteria

Inclusion criteria

• Age of 18 years of older;

• Male

• Diabetes mellitus type 2 on intensive insulin treatment (three times short acting and once daily long acting) (unchanged for > 10 weeks prior to consent)

• Stable glucose regulation last 6 months (HbA1c > 6.5% - < 9.0%)

• Stable lipid lowering therapy last 2 months (no changes in regiment or dose)

Exclusion criteria

• Current smoking

• Impaired renal function (MDRD <60 ml/min/1.73 m2)

• Recent cardiovascular event (< 6 months) (myocardial infarction, coronary artery bypass grafting, stroke)

• Severe hyperglycemic events in the past 6 months (hyperglycemia >20 mmol/l requiring hospital admittance)

• Recent or current use of PCSK9 inhibitors

• HIV-infection

• Uncontrolled hypothyroidism

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-09-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43374
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6521
NTR-old	NTR6709
CCMO	NL58836.101.16
OMON	NL-OMON43374

Study results