Effects of SUlodexide on Postprandial lipidmetabolism in patiEnts with diabetes mellitus type II; Reversing dyslipidemia

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To investigate whether treatment with sulodexide can reverse postprandial dyslipidemia in patients with type 2 diabetes mellitus

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON41342

Source
ToetsingOnline

Brief title
SUPER study

Condition

- Diabetic complications

Synonym
cholesterol, diabetes

Research involving
Human

Sponsors and support

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

Intervention

Keyword: lipolysis, postprandial clearance, sulodexide, type 2 diabetes mellitus

Outcome measures

Primary outcome

Aim of the study is to investigate whether 2 months of oral sulodexide

treatment normalizes postprandial hypertriglyceridemia in patients with DM type

II on statin treatment.

Secondary outcome

The second objective of the present study is to measure the effect of

sulodexide on adipose tissue markers of lipolysis (ANGLPTL3, GPIHBP1 and LPL)

in relation to periferal lipolysis (heparin challenge for LPL release)

Study description

Background summary

Type 2 diabetes mellitus (DM2) is associated with changes in cholesterolmetabolism, resulting in increased (postprandial) triglycide levels. Although plasma triglyceride levels are associated with increased cardiovascular risk, there are currently no effective therapies to lower plasma triglycerides in subjects with type 2 diabetes mellitus. Previous research from our group has shown that DM2 is associated with decreased endothelial heparansulfate chains, which normally clear lipids from the circulation. We thus would like to investigate whether supplementation of oral heparansulfates normalises postprandial hypertriglyceridemia in subjects with type 2 diabetes mellitus.

Study objective

To investigate whether treatment with sulodexide can reverse postprandial dyslipidemia in patients with type 2 diabetes mellitus

Study design

DM2 patients without organdamage and at stable treatment regiment of oral antidiabetic/cholesterol lowering medication will be randomized to sulodexide 200mg once daily or placebo. At baseline and after 2 months of treatment we will test efficacy of sulodexide on postprandial triglyceride clearance and peripheral lipolysis (subcutaneous biopsy) .

Intervention

Sulodexide is a commercially available oral heparanoid compound consisting of heparan sulphate (80%) and dermatan sulphate (20%)

Study burden and risks

Since our previous study with oral sulodexide (SUGAR study, see Broekhuizen Diabetologia 2010) which showed almost no side effects upon using sulodiexe, we thinkt that the increased pathophysiological insight and potential new therapeutic treatment options using sulodexide for DM2 associated dyslipidemia outweight the minimum risk (mildly increased bleedingtendency and painfull bruise after subcutaneous fatbiopsy)

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

- Male
- Age between 18 and 65 years
- willing to stop ATII/ACE inhibitors 5 days before each lipidload;- oral antidiabetes medication and on statin therapy (no insulin therapy)

Exclusion criteria

- Smoking;- Immunosuppressive drugs;- Serious previous illnesses;- Coagulation disorder;- Primary dyslipidemias;- BMI > 33 kg/m2;- Hypertension (systolic > 140 mm Hg or diastolic > 90 mm Hg);- Cardiovascular disease: ;- AMI;- CVA/ TIA;- AP ;- Intermittent claudication ;- Aneurysms of the aorta

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2014
Enrollment:	20

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Vessel
Generic name:	Sulodexide

Ethics review

Approved WMO Date:	31-05-2012
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	EUCTR2012-000381-37-NL
CCMO	NL39586.018.12