# Effects of SUlodexide on damaged endothelial Glycocalyx in pAtients with diabetes Mellitus type two: Reversing damage

Submission date Recruitment status Prospectively registered 28/12/2006 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 28/12/2006 Completed [X] Results [ ] Individual participant data Last Edited Condition category Nutritional, Metabolic, Endocrine 05/11/2010

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number

1

# Study information

Scientific Title

#### **Acronym**

**SUGAR** 

#### **Study objectives**

#### **Primary Objective:**

Aim of the study is to investigate whether sulodexide treatment reverses damage of the systemic glycocalyx in patients with Diabetes Mellitus type two (DM type II). The effect of sulodexide will be addressed in this prospective cross-over study measuring systemic and local glycocalyx volume, vascular permeability as well as endothelial function in patients with DM type II who have microalbuminuria and in patients with DM type II who do not have microalbuminuria.

#### Secondary Objective(s):

The second objective of the present study is to measure the effect of sulodexide on biochemical parameters, including micro-albuminuria and HBA1c, in patients with DM type II with and without microalbuminuria.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The study has been approved by the medical ethics commission of the Academic Medical Centre on December 20, 2006 (ref: MEC 06/ 228).

#### Study design

Randomised, placebo controlled, crossover, single blinded trial

#### Primary study design

Interventional

## Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Diabetes Mellitus type two (DM type II)

#### Interventions

Sulodexide versus placebo.

Patients with DM type II and healthy volunteers will visit the hospital on four occasions:

- 1. Screening-inclusion visit
- 2. End of study period I
- 3. End of washout visit
- 4. End of study period II

At the end of each study period, we will evaluate glycocalyx volume and vascular permeability using dextran-40 and albumine-I125 for estimation of perm- versus charge selectivity. In addition, we will evaluate vascular function as well as routine laboratory parameters, including micro-albuminuria and safety parameters.

#### Intervention Type

Drug

#### Phase

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

Sulodexide

#### Primary outcome(s)

The difference in systemic glycocalyx volume after sulodexide and after placebo treatment.

#### Key secondary outcome(s))

1. The difference in systemic glycocalyx volume after sulodexide and after placebo treatment in local sublingual glycocalyx volume, vascular permeability and endothelial function in all patients.

2. The percentage change from baseline to end of the study in microalbuminuria in patients with DM type II who have microalbuminuria.

#### Completion date

01/12/2007

# **Eligibility**

#### Key inclusion criteria

- 1. Male
- 2. Age between 18 and 65 years

#### Participant type(s)

Patient

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

Male

#### Key exclusion criteria

- 1. Smoking
- 2. Immunosuppressive drugs
- 3. Serious previous illnesses
- 4. Coagulation disorders
- 5. Primary dyslipidemias
- 6. Body Mass Index (BMI) more than 30 kg/m^2
- 7. Hypertension (systolic more than 140 mmHg or diastolic more than 90 mmHg)

#### Date of first enrolment

# Date of final enrolment 01/12/2007

#### Locations

#### Countries of recruitment

Netherlands

Study participating centre
Academic Medical Center (AMC) Amsterdam
Amsterdam
Netherlands
1100 DD

# Sponsor information

#### Organisation

Academic Medical Center (AMC) (The Netherlands)

#### **ROR**

https://ror.org/03t4gr691

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Alfa Wassermann (Italy)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults01/12/2010YesNo