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

Submission date	Recruitment status
28/12/2006	No longer recruiting
Registration date	**Overall study status**
28/12/2006	Completed
Last Edited	**Condition category**
05/11/2010	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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).

Primary study design
Interventional

Study design
Randomised, placebo controlled, crossover, single blinded trial

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

01/11/2006

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC) Amsterdam
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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 type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010		Yes	No