Postprandial effects of dapagliflozin on lipemia and inflammation

No registrations found.

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

Summary

ID

NL-OMON21590

Source
NTR

Brief title
PLEIADES-dapa

Health condition

Type 2 Diabetes Mellitus

Sponsors and support

Primary sponsor: Franciscus Gasthuis, Rotterdam
Source(s) of monetary or material Support: AstraZeneca

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary endponts are the effect of 12 weeks of treatment with dapagliflozin 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, a SGLT2-inhibitor (empagliflozin) showed a significant reduction in cardiovascular mortality without a clear mechanism for this reduction. We aim to explore the inflammatory changes of dapagliflozin compared with placebo on postprandial lipemia and postprandial leukocyte activation, oxidative stress and endothelial function in men with type 2 diabetes mellitus using insulin.

Study objective

Treatment with dapagliflozin 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

12 weeks treatment with either daily 10 mg dapagliflozin or daily matching placebo.

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

Contacts

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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%)

• Provision of informed consent prior to any study procedure

Exclusion criteria

• Current smoking

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

• Recent use of SGLT-2 inhibitor (past 6 months)

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

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

• Involvement in the planning and/or conduct of the study (applies to both AstraZeneca staff and/or staff at the study site)

• Previous enrollment in the present study

• Participation in another clinical study with an investigational product during the last 6 months

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):	01-09-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-08-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46285
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6335
NTR-old	NTR6651
CCMO	NL57393.101.16
OMON	NL-OMON46285

Study results