Dapagliflozin on cholesterol metabolism in DM2: dissecting its effect on dyslipidemia by using stable isotope based cholesterol and glucose fluxes

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28993

Source
NTR

Brief title
DICE

Health condition

diabetes type 2
dyslipidemia

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: Astrazeneca

Intervention

Outcome measures

Primary outcome

Our primary endpoint is effect of 5 weeks SLGT2 inhibition on LDL cholesterol synthesis in patients with DM2.

Secondary outcome

Secondary endpoints are effect of SGLT2 inhibition on triglyceride and cholesterol fluxes as well as (hepatic and peripheral) insulin sensitivity and energy expenditure. Finally, effect of SGLT2 inhibition on dietary intake, liver fat content (MRI liver) and fecal microbiome will be studied at these timepoints.

Study description

Background summary

Type 2 diabetes is associated with an increased cardiovascular risk. Although two the recently published trials have suggested a beneficial effect on all cause cardiovascular mortalitity upon SGLT2 inhibition, a known (class) side effect in worsening of dyslipidemia in all DM2 patients. We thus aim to dissect the effect of SGLT2 inhibition (Dapagliflozin 10mg once daily for 5 weeks) on glucose and lipid fluxes in uncomplicated DM2 subjects.

Study objective

Type 2 diabetes is associated with an increased cardiovascular risk. Besides metformin, a new treatment strategy is oral SGLT2 inhibition (dapagliflozon), Although two recently published, first-in-class cardiovascular outcome trials (EmparegMPA-REG OUTCOME and TECOS trial) have has suggested a beneficial effect on all cause cardiovascular mortalitity upon SGLT2 inhibition, a known (class) side effect in worsening of dyslipidemia in all DM2 patients. We thus aim to dissect the effect of SGLT2 inhibition (Dapagliflozin 10mg once daily for 5 weeks) on glucose and lipid fluxes in uncomplicated DM2 subjects.

Study design

0 and 5 weeks

Intervention

dapagliflozin 10mg once daily

Contacts

Public

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Eligibility criteria

Inclusion criteria

-Male or postmenopauzal female patients ;

-Type 2 diabetes mellitus(HbA1C ≥6.5% - <8.5%)

-At least 12 weeks of stable dose metformin treatment, FPG<13.2 mmol/l -LDL cholesterol >2.5 mmol/l

-Willing to switch used statin to rosuvastatin 10mg once daily

-18-75 years of age

-Ability to provide informed consent

Exclusion criteria

History of cardiovascular event

-Smoking

-exogenous insulin use

-Creatinin clearance < 60ml/min

-Alcohol abuse (>4 units/day)

-AST or ALT elevation (>2.5x upper limit)
-Contraindication to MR scanning (i.e. pacemaker, metallic foreign body, claustrophobia)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	12
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	29-08-2016
Application type:	First submission

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
NTR-new	NL5783
NTR-old	NTR6066
Other	- : 2016/16

Study results