Aspirin sensitivity in diabetes mellitus; the role of glycaemic control and dosing

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Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON31925

Source
ToetsingOnline

Brief title
ASSIGN

Condition

- Coronary artery disorders
- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
diabetes mellitus, Type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting Asklepios

Intervention

Keyword: Aspirin, Dosingschedule, Glycaemic control, Type 2 diabetes

Outcome measures

Primary outcome

The main study parameter is the prevalence of laboratory acetylsalicylic acid

resistance in patients stratified by level of glycaemic control.

Secondary outcome

The secondary endpoint is the ability of increased dosing to overcome

hyperglycaemia-associated acetylsalicylic acid resistance.

Study description

Background summary

Aspirin (acetylsalicylic acid) is the cornerstone of primary and secondary cardiovascular disease prevention, but its preventive effects are reduced in the presence of diabetes mellitus. Whether hyperglycaemia plays an important role in the reduced anti-aggregating effects of acetylsalicylic acid in diabetes remains unclear.

Study objective

The main objective of this study is to determine the role of glycaemic control in diabetes mellitus in the occurrence of acetylsalicylic acid resistance, the secondary objective is to determine the effect of increased dosing on acetylsalicylic acid resistance in diabetes mellitus.

Study design

Diagnostic, non-randomized, open label, pharmacodynamics study

Intervention

All included subjects will be assigned to increasing doses of acetylsalicylic acid. The dosing will start at 30 mg of acetylsalicylic acid daily for ten

days, followed by 100 mg of acetylsalicylic acid for ten days, after which the dose will increase to 300 mg of acetylsalicylic acid daily for ten days.

Study burden and risks

Included subjects will visit the AMC hospital on five different occasions:
Visit 1: Screenings visit, informed consent, medical history, vital signs
Visit 2: Baseline laboratory measurements, start study medication
Visit 3: Laboratory measurements, start second dosing schedule of study medication
Visit 4: Laboratory measurements, start third dosing schedule of study medication
Visit 5: Laboratory measurements, end of study
At visit 2-5 subjects will be asked to come to the laboratory in a fasting state and approximately 52.5 ml of blood will be drawn each visit.
This study will provide new insight on the effect of acetyl salicylic acid therapy on platelets in the diabetic patient, elucidating the role of glycaemic control and the possibility of increased dosing to establish the desired platelet inhibitory effect. This insight is needed to determine the optimal strategy of cardiovascular disease prevention in diabetic patients, a group of patients at high risk of developing this complication.

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

Age > 18 years
Diagnosis of type 2 diabetes according to ADA criteria

Exclusion criteria

Current acetylsalicylic acid therapy
Use of any medication interfering with platelet function, e.g. diclofenac, naproxen or clopidogrel
Allergy or hypersensitivity to prostaglandinsynthetase inhibitors
Hemorrhagic stroke in medical history
Gastric complaints or gastritis/ulcus pepticum
Severe liver or kidneyfailure

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-04-2008
Enrollment:	140
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Aspirin
Generic name:	Acetylsalicylic acid
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	25-04-2008
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	EUCTR2008-001308-22-NL
CCMO	NL22347.018.08