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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26330

Bron
NTR

Verkorte titel
ASSIGN

Aandoening

Diabetes mellitus
Cardiovascular disease

Ondersteuning

Primaire sponsor: Prof. dr. J.B.L. Hoekstra
Dept. of Internal Medicine
Academic Medical Centre
Overige ondersteuning: Fund=initiatior=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of this study is the prevalence of laboratory measured aspirin resistance stratified by level of glycaemic control

Toelichting onderzoek

Achtergrond van het onderzoek

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. 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.

To this end 105 patients with type 2 diabetes will be assigned to increasing doses of aspirin, during which the laboratory measured platelet response will be determined. Also, 35 healthy volunteers will undergo the same treatment.

Doel van het onderzoek

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. 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.

Onderzoeksopzet

T=0 (baseline): platelet aggregationtests + thromboxane measurements + start study medication (aspirin 30 mg daily)

T= 10: repeat platelet aggregationtests + thromboxane measurements + start aspirin 100 mg daily

T= 20: repeat platelet aggregationtests + thromboxane measurements + start aspirin 300 mg daily

T= 30: repeat platelet aggregationtests + thromboxane measurements_ End of study.

Onderzoeksproduct en/of interventie

All included subjects will receive three dosingregimens of aspirin treatment;

starting at 30 mg per day for ten days,

followed by 100 mg per day for ten days

and finally 300 mg per day for ten days

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 18 years

2. Diagnosis of type 2 diabetes

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current acetylsalicylic acid therapy

2. Use of any medication interfering with platelet function, e.g. diclofenac, naproxen or clopidogrel in the two weeks prior to the study.

3. Abnormal platelet count, < 100.000/ mm3

4. Allergy or hypersensitivity to prostaglandinsynthetase inhibitors

5. Hemorrhagic stroke in medical history

6. Gastric complaints or gastritis/ulcus pepticum, history of gastric bleeding

7. Known coagulation disorders

8. Severe liver or kidneyfailure

9. Substance abuse

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2008

Aantal proefpersonen:	140
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-04-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1228
NTR-old	NTR1273
Ander register	: ASSIGN
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A