

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

No registrations found.

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

Summary

ID

NL-OMON26330

Source

NTR

Brief title

ASSIGN

Health condition

Diabetes mellitus
Cardiovascular disease

Sponsors and support

Primary sponsor: Prof. dr. J.B.L. Hoekstra

Dept. of Internal Medicine
Academic Medical Centre

Source(s) of monetary or material Support: Fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

The secondary outcome is the ability of increased dosing to overcome laboratory measured aspirin resistance in type 2 diabetes mellitus.

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. 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.

Study objective

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.

Study design

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

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

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

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

Intervention

All included subjects will receive three dosing regimens 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

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 18 years
2. Diagnosis of type 2 diabetes

Exclusion criteria

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, $< 100.000/ \text{mm}^3$
4. Allergy or hypersensitivity to prostaglandin synthetase 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 kidney failure
9. Substance abuse

Study design

Design

| | |
|---------------------|-------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2008 |
| Enrollment: | 140 |
| Type: | Anticipated |

Ethics review

Positive opinion

Date: 11-04-2008

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 | NL1228 |
| NTR-old | NTR1273 |
| Other | : ASSIGN |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

Study results

Summary results

N/A