Effects of aspirin on markers of inflammation and coagulation in subclinical atherosclerosis in type 2 diabetic subjects.

No registrations found.

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

Summary

ID

NL-OMON23321

Source
Nationaal Trial Register

Brief title
DIASP study

Health condition

Diabetes Mellitus type 2, no cardiovascular disease.

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC), department of General Internal Medicine
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Markers of vascular wall inflammation, represented by hsCRP and Il-6.

Secondary outcome

1. Prostaglandin production, represented by 11-dehydro-thromboxaneB2, 8-isoprostaglandineF2á and 2,3-dinor-6-keto-prostaglandineF1á measured in morning-urine samples;

2. Vascular wall adhesion molecules, represented by sICAM-1, p-selectin, MCSF, CD40L;

3. Coagulation markers, represented by fibrinogen, vWillebrand Factor and PAI-1 activity.

Study description

Background summary

The DIASP study is a study with a prospective, randomised, placebo controlled, double blind, crossover study design, concerning the effects of aspirin (ASA) on markers of inflammation and coagulation in subclinical atherosclerosis in type 2 diabetic subjects. At random, forty patients will receive aspirin in low or intermediate dose in one period and placebo in the other period.

Study objective

An early intervention with low-dose aspirin in asymptomatic diabetic subjects attenuates progression of atherosclerosis, by decreasing inflammation and coagulation.

Study design

N/A

Intervention

Subjects will be randomised between aspirin 100 mg and 300 mg. During the study period, each group will be followed 16 weeks. Treatment with aspirin (100 or 300 mg) or placebo for 6 weeks will be followed by a washout period of 4 weeks. After the washout period, patients will be treated by placebo when they received aspirin during the first period, and aspirin when they received placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diabetes mellitus type 2;

2. Age >18 year;

3. HbA1c < 10%;

4. HsCRP >1.0 mg/l .

Exclusion criteria

1. History of myocardial infarction, percutaneous transluminal coronary angioplasty, coronary artery bypass grafting, proven manifest coronary artery disease, angina pectoris, heart failure or severe cardiac arrhythmia;

2. History of cerebrovascular accident, transient ischemic attack;

3. History of peripheral vascular disease, ankle/arm index < 1.0, history of partial ileal bypass surgery;

4. Uncontrolled hypertension;

5. Asthma;

6. Any bleeding disorder;

7. History of gastrointestinal tract bleeding;

8. Severe renal or hepatic dysfunction;

9. Pregnancy;

10. Recent participation in other research projects;

11. Recent blood donation;

12. Known allergy to salicylic acid;

13. Use of all NSAID’s;

14. Use of any antithrombotic medication;

15. Use of corticosteriods;

16. Use of HMG-CoA-reductaseinhibitors.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-04-2005
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	11-09-2005
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	NL267
NTR-old	NTR305
Other	: P03-154
ISRCTN	ISRCTN84139732

Study results

Summary results

1. J Thromb Haemost. 2007 Jul;5(7):1562-4. Epub 2007 Apr 19.
2. Diabetes Obes Metab. 2008 Aug;10(8):668-74. Epub 2007 Nov 22.