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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/12/2005		Protocol		
Registration date 20/12/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
03/07/2009	Nutritional. Metabolic. Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Marcel M.C. Hovens

Contact details

Leiden University Medical Center Department of General Internal Medicine P.O. Box 9600 Leiden Netherlands 2300 RC

Additional identifiers

Protocol serial number

NTR305; P03-154

Study information

Scientific Title

Acronym

DIASP study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised double-blind placebo controlled crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus type 2 (DM type 2)

Interventions

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.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Aspirin

Primary outcome(s)

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

Key secondary outcome(s))

- 1. Prostaglandin production, represented by 11-dehydro-thromboxaneB2, 8-isoprostaglandineF2a and 2,3-dinor-6-keto-prostaglandineF1a 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

Completion date

31/03/2006

Eligibility

Key inclusion criteria

- 1. Diabetes mellitus type 2
- 2. Aged greater than 18 years
- 3. HbA1c less than 10%
- 4. High sensitivity C-reactive protein (hsCRP) greater than 1.0 mg/l

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Kev 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 ischaemic attack
- 3. History of peripheral vascular disease, ankle/arm index less than 10, 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 non-steroidal anti-inflammatory drugs (NSAIDs)
- 14. Use of any anti-thrombotic medication
- 15. Use of corticosteriods
- 16. Use of HMG-CoA-reductase inhibitors

Date of first enrolment

27/04/2005

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

ROR

https://ror.org/027bh9e22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Centre (LUMC) (Netherlands) - Department of General Internal Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2007		Yes	No
Results article	results	01/08/2008		Yes	No