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

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
27/04/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key 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)

Sponsor details
Albinusdreef 2
P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type
University/education

Website

http://www.lumc.nl/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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