

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

**Submission date**  
20/12/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
20/12/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
03/07/2009

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

## 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

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2300 RC

## 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 corticosteroids
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?
<a href="#">Results article</a>	results	01/07/2007		Yes	No
<a href="#">Results article</a>	results	01/08/2008		Yes	No