

Aspirin and simvastatin Combination for Cardiovascular Events Prevention Trial in Diabetes

Submission date 18/01/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 05/03/2007	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 24/07/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

FARM57W8MN

Study information

Scientific Title

A randomised study of the efficacy of low-dose aspirin in the prevention of cardiovascular events in subjects with diabetes mellitus treated with statins

Acronym

ACCEPT-D

Study objectives

To assess the effects of low dose aspirin on the incidence of major vascular events, in a wide range of people with type one or type two diabetes with no clinical evidence of vascular disease and receiving statins treatment.

Please note that as of 11/02/2009 this record was updated to include amended trial dates. The initial trial dates at the time of registration were:

Initial anticipated start date: 12/03/2007

Initial anticipated end date: 12/09/2013

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 11/02/2009: Ethics Committee of the A.S.O. San Luigi Gonzaga, Orbassano (Italy) gave approval on the 2nd April 2007 (ref: 8143)

Study design

Open-label randomised parallel-group study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Type one and two diabetes mellitus

Interventions

Treatment arm: aspirin 100 mg/day per os (orally) until the achievement of the pre-established number of cardiovascular events (515 events; about five years)

Control arm: no aspirin given

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Aspirin, simvastatin

Primary outcome measure

To assess the effects of low dose aspirin on the incidence of major vascular events (defined as a combined end-point of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, or inpatient or outpatient hospital admission for cardiovascular causes, including acute coronary syndrome, not planned revascularisation procedures, peripheral vascular disease), in a wide range of people with type one or type two diabetes with no clinical evidence of vascular disease and receiving statins treatment.

Secondary outcome measures

1. Total and cause specific mortality
2. Venous thromboembolic episodes
3. Major haemorrhagic episodes
4. Total number of hospitalisations for cardiovascular causes (myocardial infarction, stroke, acute coronary syndrome, not planned revascularisation procedures, heart failure, transient ischaemic attack, peripheral vascular disease, lower limb revascularisation procedures)

Overall study start date

22/10/2007

Completion date

30/04/2015

Eligibility

Key inclusion criteria

1. Written informed consent to participate in this study
2. Clinical diagnosis of type one or type two diabetes, irrespective of diabetes treatment
3. Need for statin treatment:
 - 3.1. Patients already receiving statin therapy irrespective of their actual low density lipoprotein (LDL) cholesterol and total cholesterol levels, or
 - 3.2. Patients not currently on statin treatment with LDL cholesterol levels more than or equal to 110 mg/dL persisting after three months of dietary advice
4. Ability and willingness to comply with all study requirements
5. Male and female subjects aged greater than or equal to 50 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

5170

Key exclusion criteria

1. Previous major vascular events (non-fatal myocardial infarction, non-fatal stroke, angina, transient ischaemic attack, revascularisation procedures, peripheral vascular disease)
2. Unstable metabolic control (HbA1c more than 14.0%)
3. Any condition requiring elective treatment with aspirin
4. Contraindications to aspirin
5. Contraindications to simvastatin
6. Chronic therapy with non-steroidal anti-inflammatory drugs (NSAIDs)
7. Presence of any life-threatening condition
8. Child-bearing potential (pre-menopausal women not using reliable contraception)
9. History of active substance or alcohol abuse within the last year

Date of first enrolment

22/10/2007

Date of final enrolment

30/04/2015

Locations

Countries of recruitment

Italy

Study participating centre

Department of Clinical Pharmacology and Epidemiology

S. Maria Imbaro

Italy

66030

Sponsor information

Organisation

Consortium Mario Negri South (Consorzio Mario Negri Sud) (Italy)

Sponsor details

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Sponsor type

Research organisation

Website

<http://www.negrissud.it>

ROR

<https://ror.org/01qd3xc93>

Funder(s)

Funder type

Government

Funder Name

Italian Ministry of Health (Italy) - public funding grant received

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?
Protocol article	Study protocol	28/08/2007		Yes	No