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Aspirin and simvastatin Combination for Cardiovascular Events Prevention Trial in Diabetes

Submission date 18/01/2007	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/03/2007	**Overall study status** Completed	
Last Edited 24/07/2020	**Condition category** 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
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
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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.negrisud.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