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Dutch Acarbose Intervention Trial (DAISI)

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/03/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Giel Nijpels

Contact details
Department of general practice
EMGO Institute
VU University Medical Center
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 4449659
g.nijpels@vumc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
DAISI

Study objectives
Approximately 1/3 of persons with impaired glucose tolerance (IGT) develops type 2 diabetes mellitus in 5 - 10 years time. Acarbose is an alpha-glucosidase inhibitor decreasing post-prandial glucose levels, without the risk of hypoglycemia. The prevention of diabetes with acarbose in this study was considered a feasible approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes Mellitus type II (DM type II)

Interventions
Acarbose used at a fixed dose of 50 mg. The daily maintenance dose was 50 mg three times a day (tid), which was reached as from week 3 after two weeks of up-titration with 50 mg once a day (od) (week 1) and 50 mg twice daily (bid) (week 2).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Venous plasma glucose level two hours after oral intake (in five minutes) of 75 g glucose dissolved in 300 ml water at study end (ie, after three years). A difference in two hour post-load glucose level between placebo and acarbose group of 0.5 mmol/L was regarded as being clinically relevant.

Secondary outcome measures
1. Fasting venous glucose level
2. Appearance of type 2 diabetes mellitus and normal glucose tolerance, according to WHO criteria
3. B-cell function and insulin sensitivity as assessed via the method of the hyperglycaemic clamp
4. Level of cardiovascular risk factors: cholesterol, high density lipoprotein (HDL)cholesterol, triglycerides, lipoprotein (a) (later deleted by amendment no. 4), albumin/creatinine ratio in time assessed urine sample

Overall study start date
01/06/1996

Completion date
01/01/2000

Eligibility

Key inclusion criteria
Persons with impaired glucose tolerance on the basis of two oral glucose tolerance tests (World Health Organization [WHO] 1985 criteria).

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
119

Key exclusion criteria
1. Not having side effects of acarbose in the qualification period of three months
2. Persons having endocrinological diseases, or having a malignancy

Date of first enrolment
01/06/1996

Date of final enrolment
01/01/2000

Locations

Countries of recruitment
Netherlands

Study participating centre
Department of general practice
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
Bayer Medical B.V. (The Netherlands)

Sponsor details
P.O. Box 80
Mijdrecht
Netherlands
3640 AB

Sponsor type
Industry

ROR
https://ror.org/01442sk86

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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