Dutch Acarbose Intervention Trial (DAISI).

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27395

Source
Nationaal Trial Register

Brief title
DAISI

Health condition

Type 2 diabetes.

Sponsors and support

Primary sponsor: Bayer medical B.V.

Intervention

Outcome measures

Primary outcome

Venous plasma glucose level 2 hours after oral intake (in five minutes) of 75 g glucose dissolved in 300 ml water at study end (ie, after 3 years);

A difference in 2h post-load glucose level between placebo and acarbose group of 0.5 mmol/L was regarded as being clinically relevant.

Secondary outcome

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 hyperglycemic clamp;

4. Level of cardiovascular risk factors:

cholesterol, HDL-cholesterol, triglycerides, lipoprotein (a) (later deleted by amendment no. 4), albumin/creatinine ratio in time assessed urine sample.

Study description

Background summary

A total of 171 subjects were screened and 121 subjects with impaired glucose tolerance were included in the randomized, double-blind and placebo-controlled treatment phase over 3 years (60 placebo and 61 acarbose).

33 subjects under placebo and 27 subjects under acarbose completed the study. All randomized subjects were included in the safety population, 118 subjects (58 placebo, 60 acarbose) in the ITT population and 71 subjects (39 placebo, 32 acarbose) in the PP population.

Median age of subjects in the safety population was 56 years (placebo) and 61 years (acarbose), respectively. The sex ratio in each of the treatment groups was nearly 1:1.

Descriptively, the mean post-load glucose value after 3 years of treatment was slightly lower among subjects under acarbose compared with placebo, but in all analyzed parameters of glucose metabolism - including the oGGT data, the results derived from the hyperglycemic clamp, and the conversion rates- there appeared to be no clear and relevant differences between treatment groups.

Study objective

Approximately 1/3 of persons with 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.

Study design

N/A

Intervention

Acarbose used at a fixed dose of 50 mg. The daily maintenance dose was 50 mg tid, which was reached as from Week 3 after 2 weeks of up-titration with 50 mg od (Week 1) and 50 mg bid (Week 2).

Contacts

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Eligibility criteria

Inclusion criteria

Persons with impaired glucose tolerance on the basis of two oral glucose tolerance tests (WHO '85) crietria).

Exclusion criteria

Not having side effects of acarbose in the qualification period of 3 months. Persons having endocrinological diseases, or having a malignancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-06-1996
Enrollment:	119
Type:	Unknown

Ethics review

Positive opinion

Date:	26-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL118
NTR-old	NTR150
Other	: N/A
ISRCTN	ISRCTN33274262

Study results

Summary results
N/A