Dutch Acarbose Intervention Trial (DAISI).

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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...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27395

Bron
Nationaal Trial Register

Verkorte titel
DAISI

Aandoening

Type 2 diabetes.

Ondersteuning

Primaire sponsor: Bayer medical B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-06-1996
Aantal proefpersonen:	119
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	26-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A