

# Dutch Acarbose Intervention Trial (DAISI)

<b>Submission date</b> 20/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/03/2008	<b>Condition category</b> 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

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## Additional identifiers

## 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

### **Study type(s)**

Screening

### **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(s)**

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.

### **Key secondary outcome(s)**

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

### **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

## Healthy volunteers allowed

No

## Age group

Not Specified

## Sex

Not Specified

## 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)

**ROR**

<https://ror.org/01442sk86>

## **Funder(s)**

**Funder type**

Not defined

**Funder Name**

Not provided at time of registration

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration