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# Investigation of the effects of postprandial glucose reduction by acarbose on insulin sensitivity and cardio-vascular markers in the subjects with different stages of glucose tolerance

| Submission date | Recruitment status |
|---|---|
| 11/06/2010 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 29/06/2010 | Completed |
| **Last Edited** | **Condition category** |
| 03/06/2013 | Nutritional, Metabolic, Endocrine |

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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
BfArM N: 4022119

# Study information

### Scientific Title
Single centre, double-blind, randomised, placebo controlled, cross-over study to investigate the effects of postprandial glucose reduction by acarbose on insulin sensitivity and cardio-vascular markers in type 2 diabetes patients, subjects with impaired glucose tolerance and normal glucose tolerant subjects

### Acronym
Acarbose-Adiponectin Study

### Study objectives
We aimed to investigate whether a decreased postprandial glucose excursion and portal concentration of insulin by acarbose may improve insulin sensitivity (whole body and local, hepatic insulin sensitivity) and influence the circulating adiponectin levels (as other insulin sensitivity and cardiovascular disease [CVD] markers) in the subjects with different stages of glucose tolerance.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Ethical Committee of Potsdam University approved on the 28th January 2004 (ref: N 9/17)
2. Ethical Committee of Brandenburg approved on the 10th March 2004 (ref: N AS-43/2004)

### Study design
Single centre double-blind randomised placebo controlled 2 x 12 weeks cross-over study with a washout period of 12 weeks

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### 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
Metabolic syndrome and associated diseases

### Interventions
Eligible patients who completed a 3-week run-in period (first wash-out phase), were randomised into two treatment sequences to receive 12 weeks of double-blind treatment. Both treatment sequences consisted of acarbose 100 mg with three main meals and placebo taking three times per day. The total study duration including the wash-out phase was 40 weeks. Patients underwent liquid meal challenges and hyperinsulinemic, euglycemic glucose clamp at weeks 0, 12, 24 and 36.

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Acarbose

### Primary outcome measure
To assess the effect of postprandial glucose reduction by acarbose on insulin sensitivity in subjects with different stages of glucose tolerance.

Measured at the start and at the end of each treatments (12 week duration).

### Secondary outcome measures
1. To assess the effects of acarbose on fasting cytokines and on postprandial glucose and insulin metabolism
2. To assess the effects on liver fat content and CVD markers

Measured at the start and at the end of each treatments (12 week duration).

### Overall study start date
02/04/2002

### Completion date
01/04/2009

## Eligibility

### Key inclusion criteria
1. Males or females, aged between 18 and 75 years inclusive
2. Newly diagnosed type 2 diabetes, or previously treated with diet and/or exercise or treated with metformin or acarbose as monotherapy or with impaired glucose tolerance (IGT)/impaired fasting glucose (IFG) or with normal glucose tolerance
3. Female patients were either non-fertile or willing to use a medically approved birth control method during the whole duration of the study
4. Body mass index (BMI) between 20 and 40 kg/m^2
5. Fasting plasma glucose (FPG) less than 15 mmol/1
6. Fasting C-peptide greater than 1 ng/ml

### Participant type(s)

Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
70 randomised patients

### Key exclusion criteria
1. On treatment with insulin, insulin secretagogues, corticosteroids (with the exception of inhaled corticosteroids), thiazolidindiones derivates and monoaminooxidase inhibitors
2. Known sensitivity to drugs similar to acarbose
3. Serum creatinine greater than 1.5 mg/dl or pre-existing end-stage nephropathy
4. On laser treatment for diabetes related retinopathy within 3 months prior to study start
5. Alanine aminotransferase (ALAT) greater than 2.5 times of normal range
6. Type 1 diabetes mellitus
7. Thyroid stimulating hormone (TSH) outside of normal range
8. Medical history or signs of chronically gastrointestinal diseases with diarrhoea, flatulence and absorption anomalies

### Date of first enrolment
02/04/2002

### Date of final enrolment
01/04/2009

## Locations

### Countries of recruitment
Germany

### Study participating centre
**German Institute of Human Nutrition Potsdam**
Nuthetal
Germany
14458

## Sponsor information

**Organisation**
Bayer Schering Pharma AG (Germany)

**Sponsor details**
c/o Dr. Peter Marx
Global Scientific Affairs Manager CVRM
Müllerstraße 170
Berlin
Germany
13353

**Sponsor type**
Industry

**Website**
http://www.bayerhealthcare.com/scripts/pages/de/index.php

**ROR**
https://ror.org/04hmn8g73

# Funder(s)

**Funder type**
Government

**Funder Name**
Federal Ministry for Education and Research (Bundeministerium für Bildung und Forschung [BMBF]) (Germany)

**Funder Name**
Firma Bayer Vital (Germany)

**Funder Name**
Firma BRAHMS AG (Germany)

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/12/2012 | | Yes | No |