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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
11/06/2010

Recruitment status
No longer recruiting

Registration date
29/06/2010

Overall study status
Completed

Last Edited
03/06/2013

Condition category
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

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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).

Key secondary outcome(s))
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).

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes