

The effect of experimental hyperglycemia and AT1 receptor blockade on renal hemodynamics in impaired glucose tolerance

Submission date
21/12/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
09/01/2008

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
29/02/2008

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Helga Frank

Contact details

Nephrology Department
Klinikum rechts der Isar
Ismaninger Strasse 22
Munich
Germany
81675

Additional identifiers

Protocol serial number

1

Study information

Scientific Title

Acronym

IGT-FRA-oo30-I

Study objectives

The study aim is to investigate whether:

1. Experimental hyperglycemia reduces renal hemodynamics (glomerula filtration rate, renal plasma flow)
2. Angiotensin II Type 1 (AT1) receptor blocker treatment prevents hyperglycemia induced changes of renal hemodynamics

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Ethical Committee of the Technical University of Munich.

Primary study design

Interventional

Study design

Single-centre, open, prospective, longitudinal, non-randomised controlled trial.

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Impaired glucose tolerance/ renal changes in prediabetes

Interventions

12 participants were recruited in each of the two groups. Statistical calculation was carried out by the Institute of Statistics, Technical University of Munich.

Participants of both groups (control and IGT-group) received the following two interventions:

1. Experimental hyperglycemia (clamp technique)
2. Valsartan (AT1 receptor blocker)(oral, taken once a day in the morning) treatment for 4 weeks. The initial dose was 80 mg/day, and the dosage was increased after 7 +/- 2 days of administration to 160 mg /day.

A safety visit was made at 5 +/- 2 days after the beginning of the study for the measurement of serum creatinine, potassium and blood pressure.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

AT1 receptor blocker

Primary outcome(s)

The following were measured at rest (U1 rest, U2 rest) and during hyperglycemic stress testing (U1 stress, U2 stress) with and without AT1 receptor blocker treatment:

1. Glomerular filtration rate (inulin clearance)
2. Renal plasma flow (Para-AminoHippurate [PAH] clearance)

U1: Without AT1 receptor blocker

U2: After a 4-week treatment with valsartan

Key secondary outcome(s)

The following were assessed at U1 and U2:

1. High-sensitivity C-Reactive Protein (CRP)
2. Adiponectin
3. HbA1c (blood tests)

U1: Without AT1 receptor blocker

U2: After a 4-week treatment with valsartan

Completion date

20/10/2006

Eligibility

Key inclusion criteria

1. Males
2. 18-70 years old
3. Impaired Glucose Tolerance (for the intervention group [IGT-Group]) (tested by the oral glucose tolerance test according to the World Health Organisation) and normoglycemic patients (for control group [healthy subjects])

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Male

Key exclusion criteria

1. Renal or liver insufficiency
2. Micro-or macro-albuminuria
3. Overt diabetes mellitus

Date of first enrolment

26/07/2005

Date of final enrolment

20/10/2006

Locations

Countries of recruitment

Germany

Study participating centre**Nephrology Department**

Munich

Germany

81675

Sponsor information

Organisation

Technical University of Munich (Germany)

ROR

<https://ror.org/02kkvpp62>

Funder(s)

Funder type

Industry

Funder Name

Novartis (International)

Alternative Name(s)

Novartis AG, Novartis International AG

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration