ISRCTN07427212 https://doi.org/10.1186/ISRCTN07427212

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

Submission date	Recruitment status	[ ] Prospectively registered
21/12/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/01/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/02/2008	Nutritional, Metabolic, Endocrine	[ ] 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

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.

Study design
Single-centre, open, prospective, longitudinal, non-randmoised controlled trial.

Primary study design
Interventional

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 creatintine, 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