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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 09/01/2008	**Overall study status** Completed	
Last Edited 29/02/2008	**Condition category** Nutritional, Metabolic, Endocrine	

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
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
26/07/2005

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Male

Target number of participants
24

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
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Sponsor information

Organisation
Technical University of Munich (Germany)

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Sponsor type
University/education

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

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