

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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-randomised 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 creatinine, 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

Germany

81675

Sponsor information**Organisation**

Technical University of Munich (Germany)

Sponsor details

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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