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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number

1

# Study information

Scientific Title

#### **Acronym**

IGT-FRA-oo30-l

#### **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