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# The influence of Telmisartan on insulin resistance and fatty liver in patients suffer from hypertension

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 09/02/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 05/03/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 05/03/2010 | 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**
InReTel

## Study information

**Scientific Title**
The influence of Telmisartan on insulin resistance and fatty liver in patients suffer from hypertension: A phase IV, randomised controlled trial.

## Acronym
InReTel

## Study objectives
To determine the efficacy of Telmisartan on insulin resistance and fatty liver in patients suffer from hypertension

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
The Saxon State Medical Association Ethics Commission (Ethikkommission bei der Sächsischen Landesärztekammer) approved on the 11th of December 2009 (ref: EK-AMG-MO-2/09-1)

## Primary study design
Interventional

## Study design
Prospective phase IV open label randomised controlled parallel group study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Insulin resistance; fatty liver; hypertension; metabolic syndrome

## Interventions
Telmisartan versus standard therapy against hypertension
Comparison of two treatment arms:
1. Intervention arm: Telmisartan 40 or 80 mg daily, oral use - dependent on compliance of patients
2. Control arm: treatment of hypertension with standard therapy w/o sartans, preferred: Amlodipin, Bisoprolol and/ or Torasemid, oral use - dependent on compliance of patients

Total duration of treatment per patient: 6 months, w/o follow-up.
The total duration of follow-up post-treatment will be 12 months.

## Intervention Type
Drug

## Phase
Phase IV

## Drug/device/biological/vaccine name(s)
Telmisartan, amlodipin, bisoprolol, torasemid

## Primary outcome(s)
Improvement of insulin resistance reflected by normalised or increased ISI-Matsuda (> 4) 6 months after treatment

### Key secondary outcome(s)
1. Improvement of insulin resistance reflected by normalised or increased ISI-Matsuda (> 4)
2. Improvement of insulin resistance reflected by normalised or decreased HOMA-IR (< 2)
3. Improvement of hypertension measured by blood pressure over 24 h
4. Improvement / normalisation of the liver enzymes (gamma-GT, ALT) measured by their serum concentrations
5. Improvement / normalisation of tissue structure of liver analyzed by sonography
6. Improvement / normalisation of the blood lipids measured by serum concentrations of triglycerids, total cholesterol, high density lipoprotein (HDL) and low density lipoprotein (LDL)
7. Improvement / normalisation of tissue structure of liver analysed by sonographyferric marker measured by serum concentrations of ferritin, iron and transferrin
8. Improvement / normalisation of Body mass index and abdominal girth
9. Improvement / normalisation of uric acid measured by the serum concentration
All secondary outcomes will be measured at 3 and 6 months after treatment with Telmisartan

### Completion date
30/09/2011

## Eligibility

### Key inclusion criteria
1. Male or female adult patients aged 18 - 70 years inclusive, legally competent
2. Written informed consent
3. Presence of arterial hypertension
4. Evidence of increased Homeostasis Model Assessment of Insulin Resistance (HOMA-IR) >2
5. Evidence of decreased Insulin Sensitivity Index (ISI-Matsuda) <4
6. Presence of increased liver enzymes
6.1. Alanine transaminase (ALT)
6.2. Gamma-glytamyl transpeptidase (gamma-GT)
7. Presence of fatty liver indicated by sonography
8. Ethnic background: caucasian
9. Presence of negative pregnancy test

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria

1. Other liver diseases: e.g. virus-induced hepatitis, hemochromatosis
2. Presence of severe increased liver enzymes as an evidence for serious liver diseases
2.1. ALT > 4 µkat/l
2.2. Aspartate Aminotransferase (AST) > 4 µkat/l
2.3. Gamma-GT > 10 µkat/l
3. Increased AST enzyme activity in comparison to ALT enzyme activity as an evidence for an alcoholic fatty liver disease (AFLD)
4. Obstructive disease of bile ducts and cholestasis
5. Pre-treatment of hypertension with sartans
6. Chronic infections with increased C-Reactive Protein (CRP) serum concentration
7. Hypersensitivity to telmisartan or another ingredient of medicinal product
8. Hereditary fructose intolerance based on sorbitol in medicinal product
9. Presence of an angioneurotic oedema during former treatment with ACE-inhibitors or angiotensin-II-receptor-antagonists
10. Presence of manifest diabetes mellitus type 2
11. Concurrent participation in any other clinical trial or participation in any other clinical trial during the previous 30 days
12. Pregnancy, lactation period or female patients seeking to become pregnant during interventional period
13. Low compliance or inability to understand instructions/study documents

### Date of first enrolment
15/02/2010

### Date of final enrolment
30/09/2011

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Department of Internal Medicine**
Chemnitz
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## Sponsor information

### Organisation
Klinikum Chemnitz gGmbH (Germany)

### ROR
https://ror.org/04wkp4f46

# Funder(s)

**Funder type**
Industry

**Funder Name**
Bayer Vital GmbH (Germany)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration