

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

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Registration date 05/03/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/03/2010	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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)

Study design

Prospective phase IV open label randomised controlled parallel group study

Primary study design

Interventional

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

Germany

09116

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