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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

Contact name
Prof Ulrich Stölzel

Contact details
Department of Internal Medicine
Klinikum Chemnitz gGmbH
Flemmingstrasse 2
Chemnitz
Germany
09116

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet.

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

Secondary outcome measures
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

Overall study start date
15/02/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72

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)

Sponsor details
c/o Prof. Dr. Stölzel (legal representative)
Flemmingstrasse 2
Chemnitz
Germany
09116

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04wkp4f46

Funder(s)

Funder type
Industry

Funder Name
Bayer Vital GmbH (Germany)

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