ISRCTN47438148 https://doi.org/10.1186/ISRCTN47438148

Renoprotection of Optimal Antiproteinuric Doses of benazepril and losartan in chronic renal insufficiency: long-term analysis

Submission date 30/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/09/2006	**Overall study status** Completed	
Last Edited 15/01/2020	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Fan Fan Hou

Contact details
1838 North Guangzhou Avenue
Guangzhou
China
510515
+86 (0) 20 6164 1597
ffhou@public.guangzhou.gd.cn

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00338091

Secondary identifying numbers
30330300

Study information

Scientific Title
Renoprotection of Optimal Antiproteinuric Doses of benazepril and losartan in chronic renal insufficiency: long-term analysis

Acronym
ROAD

Study objectives
The primary hypothesis is the optimal antiproteinuric doses of benazepril (an Angiotensin-Converting Enzyme [ACE] inhibitor) or losartan (an Angiotensin II Receptor Blocker [ARB]), as compared with their conventional doses, can safely improve the long-term renal outcome in non-diabetic patients with proteinuria and chronic renal insufficiency. The second hypothesis is that long-term renoprotection of benazepril and losartan, at their optimal antiproteinuric doses, might be similar.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nanfang Ethics Committee (reference number: 200201).

Study design
Randomised open-label parallel-assignment safety/efficacy study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nondiabetic Chronic Renal Insufficiency

Interventions
Each intervention group will be given one of the following treatments:
Drug 1: benazepril
Drug 2: losartan

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Benazepril and losartan

Primary outcome measure
The primary endpoint is time to the first event for the composite endpoint: doubling of the serum creatinine concentration, End Stage Renal Disease (ESRD) or death. Doubling of serum creatinine concentration from the baseline value (mean of all values obtained during the run-in) is confirmed by a second serum creatinine value obtained at least four weeks after the initial doubling. ESRD is defined by the need for long-term dialysis or renal transplantation.

Secondary outcome measures
Secondary endpoints include changes in urinary protein excretion rate and the progression of renal disease assessed by creatinine clearance and Glomerular Filtration Rate (GFR) as calculated by Modification of Diet in Renal Disease (MDRD) equation.

Overall study start date
01/01/2002

Completion date
01/05/2003

Eligibility

Key inclusion criteria
1. Serum creatinine concentration of 1.5 to 5.0 mg per deciliter (133 to 442 µmol/L)
2. Creatinine clearance of 20 to 70 ml per minute per 1.73 m^2, with variations of less than 30 percent in the three months before screening evaluation
3. Nondiabetic renal disease
4. Persistent heavier proteinuria (defined by urinary protein excretion of more than 1.0 g per day for three or more months without evidence of urinary tract infection or overt heart failure [a New York Heart Association class of III or IV])

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
360 participants

Key exclusion criteria

1. Immediate need for dialysis
2. Treatment with corticosteroids, non steroidal anti-inflammatory drugs, or immunosuppressive drugs
3. Hyper-or hypokalemia (serum potassium concentration 5.6 mmol per litre or more or 3.5 mmol per litre or less)
4. Renovascular disease
5. Myocardial infarction or cerebrovascular accident in the year preceding the trial
6. Connective-tissue disease and obstructive uropathy

Date of first enrolment
01/01/2002

Date of final enrolment
01/05/2003

Locations

Countries of recruitment
China

Study participating centre
1838 North Guangzhou Avenue
Guangzhou
China
510515

Sponsor information

Organisation
National Natural Science Foundation of China

Sponsor details
83 Shuangqing Road
Beijing
China
100085

Sponsor type
Research organisation

Website
http://www.nsfc.gov.cn

ROR
https://ror.org/01h0zpd94

Funder(s)

Funder type
Government

Funder Name
Peoples Liberation Army Grant for Major Clinical Research (2001, to Dr. Fan Fan Hou)

Funder Name
National Nature and Sciences Grant for Major Projects (No.30330300, to Dr. Fan Fan Hou)

Funder Name
Novartis (in part)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/06/2007	Yes	No