

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

Registration date
04/09/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
15/01/2020

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00338091

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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 $\mu\text{mol/L}$)
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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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