

# 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

### Contact name

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### Contact details

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## 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  $\mu\text{mol/L}$ )
2. Creatinine clearance of 20 to 70 ml per minute per  $1.73\text{ m}^2$ , 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?
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[Results article](#)

results

01/06/2007

Yes

No