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Leflunomide treatment in progressive Immunoglobulin A Nephropathy (IgAN), a multi-centre, prospective, randomised controlled study

Submission date
28/06/2006

Recruitment status
No longer recruiting

Registration date
28/07/2006

Overall study status
Completed

Last Edited
08/04/2008

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
N/A

Study information

Scientific Title

Study objectives
Main hypothesis: compared with prednisone separately, leflunomide combined with prednisone can reduce proteinuria, delay the progression of Chronic Kidney Disease (CKD) and preserve renal function in progressive IgAN.

Secondary hypothesis: leflunomide combined with prednisone in treatment of IgAN is safe for at least 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Renji Hospital Research Ethics Committee approval given on 25/05/2004 (reference number: [2004]12A).

Study design
Multicentre randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Progressive Immunoglobulin A (IgA) nephrology

Interventions
Please note that as of 02/07/2007, the anticipated end date of this trial has been extended to 31 /12/2007. The anticipated end date of this trial was again extended on 08/04/2008 to 31st June 2008 - this is due to problems with recruitment.

After enrolment, patients are randomised to prednisone or prednisone together with leflunomide for one year and then followed up for two years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Leflunomide, prednisone

Primary outcome(s)
Loss of renal function (defined as serum creatinine increased by 200% or a reduce of 50% in the estimated GFR)

Key secondary outcome(s))

Discontinuation of therapy due to adverse effect

Completion date
30/06/2008

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. Renal biopsy diagnosed primary IgAN in three months before enrolment and proteinuria more than one gram per 24 hours, in conjunction with a decreased renal function at diagnosis (estimated Glomerular Filtration Rate [GFR] less than 60 ml/min and more than 29 ml/min, evaluated by the Modification in Diet of Renal Disease [MDRD] equation) and/or histological unfavorable criteria (Lees classification grade II to IV)
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Rapidly progressive IgAN (IgAN with rapid decline in renal function and/or histological characterized by necrotizing capillaritis and crescent formation)
2. Secondary IgAN (e.g. clinical and history evidence of Henoch-Schönlein purpura, hepatitis related nephropathy, other renal and systemic diseases such as Systemic Lupus Erythematosus (SLE), Goodpasture syndrome, vasculitis and diabetics nephropathy)
3. The intake of immunosuppressive drugs more than one week during the last six months
4. The intake of prednisone or prednisolone more than 20 mg per day over four weeks during the last six months
5. Serum creatinine more than 250 umol/l at enrolment
6. Current signs of severe disease such as severe infection
7. Hepatitis B serology positive, except when only Hepatitis B Surface Antibody (HBsAb) positive
8. Elevation of hepatic aminotransferase
9. Previous malignancy, known Human Immunodeficiency Virus (HIV) test positive, psychiatric antecedent, active central nervous disease, severe gastrointestinal disease and other situations forbidden with immunosuppression agents

10. Abnormal in glucose metabolism, fasting glucose over 6.2 mmol/l
11. Pregnancy, breast feeding or inadequate contraception if female
12. Allergy to a study medication or reluctant to participate in the study

Date of first enrolment
01/06/2004

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
China

Study participating centre
Renji Hospital
Shanghai
China
200001

Sponsor information

Organisation
Cinkate Pharmaceutical Corporate (China)

Funder(s)

Funder type
University/education

Funder Name
Renal Division, Renji Hospital, Shanghai Jiaotong University School of Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration