ISRCTN62574616 https://doi.org/10.1186/ISRCTN62574616

A Randomised Controlled Trial of Mycophenolate Mofetil (MMF) in Patients with Immunoglobulin A (IgA) Nephropathy (IgAN)

Submission date
09/03/2004

Recruitment status
No longer recruiting

Registration date
11/03/2004

Overall study status
Completed

Last Edited
08/08/2008

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] 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

Contact name
Dr Ronald Hogg

Contact details
7777 Forest Lane
Suite C740
Dallas, Texas
United States of America
75230
+1 972 566 5575
spnsg@lonestarhealth.com

Additional identifiers

Study information

Scientific Title

Study objectives

To undertake a multicentre, randomised controlled trial designed to test the hypothesis that treatment with MMF will lead to significant and sustained improvement in proteinuria in patients with IgAN who have been pre-treated (and continue to be treated) with ACEi and FOS compared to a placebo control group of patients receiving comparable doses of ACEi and FOS without MMF.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Multicentre, double-blind placebo-controlled, randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
IgA Nephropathy

Interventions
All subjects receive lisonopril and fish oil supplements. After three months, subjects are randomised to either MMF or the placebo for one year.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mycophenolate Mofetil

Primary outcome(s)
Change from entry level in urine P/C ratio. Data for this outcome will be examined every 6 months until the end of the study two years after randomisation.

Key secondary outcome(s)
Change in estimated Glomerular Filtration Rate (estGFR). We realise that the likelihood of detecting significant changes in GFR in this short-term study is remote.

Completion date
01/01/2005

Eligibility

Key inclusion criteria
25 centres in United States and Canada:
1. Aged seven to 70
2. Renal biopsy diagnostic for IgAN based on immunohistologic staining for IgA that is greater than or equal to staining for IgG and IgM after the biopsy report has been evaluated by one of the study pathologists (entry into the study does not depend upon any specific time interval between the time of the renal biopsy and the time of entry)
3. Ability to swallow the oral medications used in the study
4. Signed informed consent by subjects aged over 18, and parent/guardian of any subject aged under 18, with a subject aged seven to 18 also signing an age-appropriate assent form
5. Urine Protein/Creatinine ratio more than or equal to 0.8 for males and more than or equal to 0.6 for females prior to randomisation
6. For female subjects of childbearing potential, a negative pregnancy test one week prior to starting lisinopril, and again less than one week before starting MMF or placebo

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Clinical and histologic evidence of systemic lupus erythematosus
2. Well-documented history of Henoch-Schonlein purpura (previous non-specific abdominal pain or rash does not exclude a subject)
3. Cirrhosis, chronic active liver disease, hepatitis B, hepatitis C
4. History of significant gastrointestinal disorder (e.g. severe chronic diarrhea or active peptic ulcer disease)
5. Human Immunodeficiency Virus (HIV)
6. Any systemic infection or history of serious infection within one month of entry
7. Absolute Neutrophil Count (ANC) less than 2000/mm^3
8. Hematocrit (HCT) less than 28% (anemic subjects may be reevaluated after the anemia has been treated)
9. Estimated glomerular filtration rate (estGFR) less than 40 ml/min/1.73m^2 at time of randomisation (it is acceptable for the estGFR to fall to less than 40 ml/min/1.73m^2 during treatment with MMF or placebo provided the level prior to randomisation is still more than or equal to 60% of the pre-entry value)
10. Known contraindication to the administration of MMF, OMACOR® or lisinopril (or losartan if used instead of lisinopril)
11. Other major organ system disease or malignancy except skin cancer fully excised more than five years prior to entry
12. Current or prior treatment with MMF or azathioprine
13. Pregnancy or breast feeding at time of entry or unwillingness to comply with measures for contraception
14. Current or recent (within 30 days) exposure to any investigational drug

Date of first enrolment
01/01/2003

Date of final enrolment
01/01/2005

Locations

Countries of recruitment
Canada

United States of America

Study participating centre
7777 Forest Lane
Dallas, Texas
United States of America
75230

Sponsor information

Organisation
Medical City Dallas Hospital (USA)

ROR
https://ror.org/059rc1n32

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Medical City Dallas Hospital (USA)

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?
Protocol article	Protocol	25/03/2004		Yes	No