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

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| **Submission date**<br>09/03/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>11/03/2004 | **Overall study status**<br>Completed | |
| **Last Edited**<br>08/08/2008 | **Condition category**<br>Urological and Genital Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# 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

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

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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.

### Secondary outcome measures
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.

### Overall study start date
01/01/2003

### 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

### Age group
Not Specified

### Sex
Both

### Target number of participants
100

### 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)

### Sponsor details

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### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/059rc1n32

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
Medical City Dallas Hospital (USA)

## 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? |
|---|---|---|---|---|---|
| Protocol article | Protocol | 25/03/2004 | | Yes | No |