

# Proteinuria in Glomerulonephritis: Myfortic® (GloMY)

<b>Submission date</b> 19/04/2010	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/05/2010	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/11/2016	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://www.bctu.bham.ac.uk/glomy>

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Elizabeth Brettell

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2009-016003-26

### IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

V2, EuDRACT No: 2009-016003-26

## **Study information**

### **Scientific Title**

Randomised pilot trial of Myfortic® for the treatment of primary proteinuric glomerulonephritis

### **Acronym**

GloMY

### **Study objectives**

To determine the feasibility of running a full-scale phase III randomised trial of Myfortic ®plus short course steroids versus standard care in patients with Focal Segmental Glomerulosclerosis (FSGS) or Immunoglobulin A Nephropathy (IgAN). The trial will also provide preliminary comparative data on the efficacy of Myfortic® plus short course steroids in inducing sustained response (partial or complete) in a well-defined cohort of patients with primary proteinuric glomerulonephritis (FSGS and IgAN) that will inform the sample size required to design a large prospective randomised study investigating the effect of Myfortic®.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

West of Scotland Ethics Committee 1, 04/05/2010, ref: 10/S0703/27

### **Study design**

National multicentre randomised controlled open label pilot trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Will be available at: <http://www.bctu.bham.ac.uk/glomy>

### **Health condition(s) or problem(s) studied**

Renal; primary proteinuric glomerulonephritis

### **Interventions**

Intervention group for both FSGS and IgAN patients (Myfortic® and short course of steroids): Myfortic® 720mg b.d. continued for 2 years, along with prednisolone, starting at dose of 1mg/kg (up to a maximum of 60mg) tapered to 0mg by 10 weeks.

Standard care for FSGS patients (High-dose steroids - prednisolone): Prednisolone, starting at dose of 1mg/kg (up to a maximum of 60mg) until complete remission or a maximum of 6 months treatment. If complete remission is achieved, prednisolone will be tapered to 0mg over the following 10 weeks. In those achieving partial remission, prednisolone will be continued for a further month, and then tapered to 5mg over 8 weeks, and then maintained at 5mg until 2 years.

Standard care for IgAN patients: No treatment.

All patients receive 2yrs treatment and are followed up until the end of the trial which is at 4yrs. So all patients will be followed up for at least two years after date of randomisation. So for patients who enter at the trial start they will have 2yrs treatment and a further 2 yrs follow-up, and patients entering at the end of the 2yr recruitment period will just have 2yrs of treatment and follow-up.

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

Mycophenolic acid (Myfortic®), prednisolone

## **Primary outcome measure**

Proportion of patients achieving complete or partial remission by 24 weeks sustained (relapse free) for 12 months.

## **Secondary outcome measures**

1. Proportion achieving partial remission
2. Time to partial remission
3. Proportion achieving complete remission
4. Time to complete remission
5. Time to relapse
6. Proportion of patients requiring alternative cytotoxic agent or treatment failure and renal function (estimated Glomerular Filtration Rate, proteinuria)
7. Treatment safety:
  - 7.1. Cumulative dose of corticosteroids
  - 7.2. Number of patients developing steroid induced diabetes
  - 7.3. Number of patients having serious infections
  - 7.4. Adverse events
  - 7.5. Markers of bone turnover
    - 7.5.1. procollagen type 1 aminoterminal propeptide (P1NP, a marker of bone formation)
    - 7.5.2.  $\beta$ -C-terminal telopeptides of type 1 collagen ( $\beta$ -CTX, a marker of bone resorption)

Data will be collected at baseline, at weeks 2 and 4, and then every 4 weeks out to 6 months post-randomisation, and then every 12 weeks for at least 2 years.  
This study will also enable the study forms to be piloted.

**Overall study start date**

01/06/2010

**Completion date**

02/10/2012

**Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

**Key inclusion criteria**

1. Patients with new onset biopsy proven (within last year) primary FSGS with albumin <30g/dl OR patients with primary IgAN with biopsy findings E1 and T<2 using the Oxford classification and a minimum of 8 glomeruli in the biopsy
2. Proteinuria (Protein Creatinine Ratio, PCR>150) following at least 4 weeks treatment with maximal blood pressure lowering therapy (to include angiotensin blockade) to target blood pressure <125/75 mmHg
3. If female and of childbearing potential, must not be pregnant or breastfeeding, and agree to avoid pregnancy during and for 6 weeks following the last dose of study treatment
4. If male with a partner of childbearing potential, must agree to use adequate, medically approved, contraceptive precautions during and for 6 weeks following the last dose of study treatment.

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Age <18 years
2. Secondary causes of FSGS
3. Secondary IgAN
4. Deteriorating renal function >20µmol/l each week for 3 weeks or more
5. Estimated Glomerular Filtration Rate (eGFR) <20 ml/min (using modification of diet in renal disease [MDRD] equation)
6. Poor blood pressure control (e.g. blood pressure ≥140/80 mmHg)
7. Previous treatment with immunosuppression therapies

- 8. Unable to receive immunosuppression treatments due to malignancy or active infection
- 9. Patients with systemic infection unless specific anti-infective therapy is employed
- 10. Diabetes
- 11. Known to have hepatitis B or C
- 12. Known to be HIV positive
- 13. Inability to give informed consent

**Date of first enrolment**

21/10/2010

**Date of final enrolment**

12/08/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Birmingham Clinical Trials Unit**

Birmingham

United Kingdom

B15 2TT

## **Sponsor information**

**Organisation**

University Hospitals Birmingham NHS Foundation Trust (UK)

**Sponsor details**

Dr. Chris Counsell

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**Sponsor type**

Not defined

**Website**

<http://www.uhb.nhs.uk/research>

**ROR**

<https://ror.org/014ja3n03>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Novartis (UK) - Educational Grant (ref: ERL080AGB09T)

## Results and Publications

**Publication and dissemination plan**

As the study showed that it was not feasible to run a full-scale phase III randomised trial of Myfortic plus short course steroids versus standard care in patients with FSGS or IgAN, and we obtained very limited data to assess the preliminary comparative efficacy of Myfortic plus short course steroids in inducing sustained response in patients with FSGS or IgAN, there are no plans for publication. The study outcome has been disseminated to all collaborators and the GloMY collaborators will all be sent a summary of this report. All participants were informed of the outcome and end of trial via a Research Ethics Committee approved letter via their clinician.

**Intention to publish date****Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study is not expected to be made available. As the study showed that it was not feasible to run a full-scale phase III randomised trial of Myfortic plus short course steroids versus standard care in patients with FSGS or IgAN, and we obtained very limited data to assess the preliminary comparative efficacy of Myfortic plus short course steroids in inducing sustained response in patients with FSGS or IgAN, there are no plans for publication.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No