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Proteinuria in Glomerulonephritis: Myfortic® (GloMY)

Submission date	Recruitment status	[X] Prospectively registered
19/04/2010	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/05/2010	Stopped	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/11/2016	Urological and Genital Diseases	[_] 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

Clinical Trials Information System (CTIS)
2009-016003-26

Protocol serial number
V2, EuDRACT No:

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

Study type(s)
Treatment

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 2rys of treatment and follow-up.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Mycophenolic acid (Myfortic®), prednisolone

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

Key secondary outcome(s))
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. β-C-terminal telopeptides of type 1 collagen (β-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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Birmingham Clinical Trials Unit
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B15 2TT

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust (UK)

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Industry

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

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes