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A randomised trial of Myfortic® versus mycophenolate in the treatment of multisystem autoimmune disease

Submission date 13/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/03/2006	**Overall study status** Completed	
Last Edited 17/09/2014	**Condition category** Musculoskeletal Diseases	

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)
2005-002207-16

Study information

Scientific Title

Acronym
MYFMAD

Study objectives
The improved tolerance of Myfortic® when compared to mycophenolate mofetil (MMF) permits higher dosing and improved disease control in multisystem autoimmune disease (MSAID)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Oxfordshire Research Ethics Committee C, reference number: 05/Q1606/140

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multisystem autoimmune disease

Interventions
Myfortic® tablets versus mycophenolate tablets given to treat multisystem autoimmune disease

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Myfortic, mycophenolate mofetil (MMF)

Primary outcome(s)
Primary efficacy:
Therapeutic failure: either disease flare or failure to achieve remission at six months (both defined by disease activity scores)
Primary tolerability:
Inability to tolerate target MMF or Myfortic® dose

Key secondary outcome(s)
1. Disease activity (British Isles Lupus Assessment Group [BILAG] or Birmingham Vasculitis Assessment Score [BVAS]) area under curve
2. Time to disease remission or time to disease flare
3. Cumulative prednisolone dose
4. All adverse events

5. Severe adverse events
6. Infections
7. Change in 36-item short-form questionnaire (SF-36) between 0 and 6 months and between 0 and 12 months

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Diagnosis of Systemic Lupus Erythematosus (SLE) or Primary Systemic Vasculitis (PSV)
2. Either:
a. About to commence MMF or
b. Established on MMF for at least three months but with inadequate disease control on MMF 2000 mg per day or less
c. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Active infection (including hepatitis B, C, Human Immunodeficiency Virus [HIV] and tuberculosis)
2. Known hypersensitivity to MMF
3. Cancer or an individual history of cancer (other than resected basal cell skin carcinoma)
4. Females who are pregnant, breast feeding, or at risk of pregnancy and not using a medically acceptable form of contraception
5. Any condition judged by the investigator that would cause the study to be detrimental to the patient
6. Use of any investigational drug within four weeks of the baseline visit
7. Patients who are planning to undergo elective surgery during the study period
8. Age <18 years

Date of first enrolment
01/09/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Vasculitis Department
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Industry

Funder Name
Research grant provided by Novartis to investigator own account - vasculitis research account

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?
Results article	results	01/12/2014		Yes	No