

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

Registration date
13/03/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
17/09/2014

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2005-002207-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2005

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

Age group

Adult

Sex

Both

Target number of participants

40

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

England

United Kingdom

Study participating centre**Vasculitis Department**

Cambridge

United Kingdom

CB2 2QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

Addenbrooke's Hospital

Research and Development Department

Box 146

Hills Road

Cambridge

England

United Kingdom

CB2 2QQ

Sponsor type

Hospital/treatment centre

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**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?
Results article	results	01/12/2014		Yes	No