ISRCTN35919612 https://doi.org/10.1186/ISRCTN35919612

Maintenance therapy in patients with severe Systemic lupus erythematosus (SLE): The BILAG multi-centre open randomised controlled trial comparing cyclosporin A and azathioprine

Submission date
18/07/2002

Recruitment status
No longer recruiting

Registration date
18/07/2002

Overall study status
Completed

Last Edited
20/01/2010

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
G0535

Study information

Scientific Title

Acronym
CYAZ

Study objectives
Added 20/01/10:
To determine whether low-dose ciclosporin was a more effective corticosteroid-sparing agent than AZA in patients with SLE.

Please note that as of 20/01/10 this record has been updated. All updates can be found in the relevant field with the above update date. This information was obtained from the publication below PMID: 20081225.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised open label active controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Systemic lupus erythematosus (SLE)

Interventions
1. Steroids tapered accordingly to protocol
2. Randomised to azathioprine or cyclosporin A
3. Dose increased according to body weight and tolerability

Added 20/01/10:
Duration of intervention was 12 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Added 20/01/10:
Absolute mean change in prednisolone

Secondary outcome measures
Added 20/01/10:
1. Change in disease activity (classic British Isles Lupus Assessment Group [BILAG] index)
2. Number of flares
3. Development of new damage
4. Change in quality of life

Overall study start date
01/06/1998

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. American Rheumatism Association (ARA) criteria for SLE
2. New corticosteroid sparing agent required
3. Patient on 15 mg or more of prednisolone for at least 4 weeks

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
89 (added 20/01/10)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/1998

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Musculoskeletal Unit
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Arthritis Research Campaign (ARC) (UK)

Sponsor details
Copeman House
St Mary's Court
St Mary's Gate
Chesterfield
Derbyshire
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info@arc.org.uk

Sponsor type
Charity

Website
http://www.arc.org.uk

ROR
https://ror.org/02jkpm469

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (UK)

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	01/04/2010		Yes	No