

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	<input type="checkbox"/> Prospectively registered
Registration date 18/07/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/01/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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 ciclosporin 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

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S41 7TD

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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