

Randomised, double-blind, placebo-controlled trial of azathioprine in moderate to severe atopic eczema

Submission date 02/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/10/2017	Condition category Skin and Connective Tissue 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Randomised, double-blind, placebo-controlled trial of azathioprine in moderate to severe atopic eczema

Study objectives

Azathioprine is a safe and effective treatment for moderate-to-severe atopic eczema.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Moderate-to-severe atopic eczema which is only partially controlled by standard therapy with topical steroids and emollients

Interventions

Adjunctive treatment with either azathioprine or placebo suspension in patients on optimal topical therapy. Patients and investigators are blinded to treatment allocation. Azathioprine dosing as per our previously published dose regime.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Azathioprine

Primary outcome measure

Change in disease activity (SASSAD score over 12 weeks).

Secondary outcome measures

1. Global response assessed by patient and investigator
2. Patient assessed itch and loss of sleep
3. Body surface area affected
4. Weight of topical steroid used
5. Soluble CD30 levels
6. Quality of life (dermatology quality of life index)

Overall study start date

01/02/2001

Completion date

01/09/2002

Eligibility

Key inclusion criteria

1. Male or female aged from 16 to 65 years inclusive
2. The diagnosis of atopic eczema will be based on the UK modification of Hanifin and Rajkas diagnostic criteria
3. Biochemistry (urea and electrolytes, Liver Function Tests [LFTs]) and Full Blood Count (FBC) are within the laboratorys reference ranges. If not, the subject can be included only on condition that the investigator judges that deviations are not clinically relevant
4. All patients will provide written informed consent to participate

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

62

Key exclusion criteria

Patients will be ineligible for entry in the study if any of the following apply:

1. Very low/undetectable Thiopurine Methyltransferase (TPMT) activity (less than 2.5 nmol/h/ml Red Blood Cells [RBC])
2. Transfusion prior to TPMT assessment
3. Concomitant unstable or serious systemic disease, including subjects known to be Human Immunodeficiency Virus (HIV) positive
4. Previous malignant disease, or serious hepatic, renal or haematological disease
5. Current heavy alcohol abuse or class A illicit drug abuse
6. The patient has had any major surgical procedure within four weeks of the intended entry

date into the trial

7. Women who are pregnant or lactating
8. Prominent infected eczema or eczema requiring systemic antibacterial treatment during the two weeks prior to trial entry
9. Use of very potent topical steroids during the two weeks prior to entry (e.g. 0.05% Clobetasol propionate [Dermovate])
10. Treatment with any of the following in the three months prior to commencing the trial:
 - a. Systemic steroids
 - b. Cyclosporin A
 - c. Mycophenolate mofetil
 - d. Topical tacrolimus
 - e. Hospital phototherapy or sunbeds
 - f. Chinese herbal medicine
 - g. Evening primrose oil
 - h. Hospital admission for the management of eczema
11. Concurrent drugs which could interact with azathioprine metabolism (rifampicin and allopurinol)
12. Mild eczema (disease activity score: Six Area Six Sign Atopic Dermatitis [SASSAD] less than 10)

Date of first enrolment

01/02/2001

Date of final enrolment

01/09/2002

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Royal Victoria Infirmary

Newcastle upon Tyne

United Kingdom

NE1 4LP

Sponsor information

Organisation

The Newcastle upon Tyne Hospitals NHS Trust (UK)

Sponsor details

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne
England
United Kingdom
NE1 4LP

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jane.varey@nuth.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Charity

Funder Name

British Skin Foundation (UK) - grant (Project number 226)

Funder Name

Wellcome Trust (UK) - indirectly via a Wellcome Research Leave Fellowship awarded to Nick Reynolds

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?
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Other publications	review of evidence	01/07/2001	Yes	No
Results article	results	11/03/2006	Yes	No