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

Submission date	Recruitment status	[_] Prospectively registered
02/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/10/2017	Skin and Connective Tissue Diseases	

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

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England
United Kingdom
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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?

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