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

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
02/09/2005				
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

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre Royal Victoria Infirmary

Newcastle upon Tyne United Kingdom NE1 4LP

Sponsor information

Organisation

The Newcastle upon Tyne Hospitals NHS Trust (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

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