Investigating whether topical application of a non toxic molecule improves epidermal pH and barrier function in atopic dermatitis

Submission date	Recruitment status	Prospectively registered
21/10/2010	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
21/10/2010	Completed	Results
Last Edited	Condition category	Individual participant data
30/09/2016	Skin and Connective Tissue Diseases	Record updated in last year

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 7064

Study information

Scientific Title

Investigating whether topical application of a non toxic molecule improves epidermal pH and barrier function in atopic dermatitis

Study objectives

It is understood that the skin of people with atopic dermatitis (AD) does not act as an efficient barrier against chemicals and microbes that can enter the skin. One of the chemicals in the skin that may be important in barrier function is called Filaggrin. This study examines whether application of a naturally-occuring molecule onto the skin of people with AD may improve the barrier function of their skin.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC, ref: 08/H1009/51

Study design

Single-centre randomised interventional trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Skin; Subtopic: Skin (all Subtopics); Disease: Dermatology

Interventions

- 1. Intervention: Gel containing a naturally-occuring chemical onto the skin of one their forearms every day for 6 weeks
- 2. Control: On the other forearm they will be asked to apply the same cream/gel that doesn't contain any of the naturally-occuring molecule

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Filaggrin

Primary outcome(s)

Each week volunteers will be asked to complete a short questionnaire (POEM)

Key secondary outcome(s))

- 1. General skin condition using a well established scoring system for AD (SCORAD)
- 2. Skin barrier function transepidermal water loss (TEWL), measured at monthly intervals

Completion date

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/09/2008

Date of final enrolment

01/01/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre The University of Manchester

Manchester United Kingdom M13 9PT

Sponsor information

Organisation

Biotechnology and Biological Science Research Council (BBSRC) (UK)

ROR

https://ror.org/00cwqg982

Funder(s)

Funder type

Research council

Funder Name

Biotechnology and Biological Sciences Research Council

Alternative Name(s)

UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, Biotechnology and Biological Sciences Research Council (BBSRC), BBSRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes