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

Submission date	Recruitment status	
21/10/2010	No longer recruiting	[ ] Prospectively registered
		[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/09/2008

Completion date
01/01/2011

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned sample size: 20

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

England

United Kingdom

Study participating centre
The University of Manchester
Manchester
United Kingdom
M13 9PT

Sponsor information

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

Sponsor details
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UA

Sponsor type
Research council

Website
http://www.bbsrc.ac.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, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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