ISRCTN35671014 https://doi.org/10.1186/ISRCTN35671014

Assessment of the effects of topical sodium cromoglicate on itch and flare in human skin

Submission date 02/09/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 21/09/2010	**Overall study status** Completed	
Last Edited 21/09/2010	**Condition category** Signs and Symptoms	

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
HHSOT.01

Study information

Scientific Title
To assess the effects of topical sodium cromoglicate on itch and flare in human skin induced by intradermal histamine: a randomised double-blind vehicle controlled intra-subject design trial

Study objectives
The intradermal injection of histamine in human skin results in a weal, flare and increased blood flux accompanied by severe itching. We have previously shown that the chromone, nedocromil sodium when introduced into the skin using iontophoresis can reduce the severity of the itch and the size of the flare, but with no effect on the weal or blood flux. We hypothesise that the related chromone, sodium cromoglicate will have the same effect both when introduced by iontophoresis and when applied topically to the skin using a new cutaneous emulsion, Altoderm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire Research Ethics Committee approved in March 2000 (ref: 00/100)

Study design
Randomised double-blind vehicle controlled intra-subject trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Itch and flare in human skin

Interventions
1. 4% sodium cromoglicate dissolved in reversed osmosis purified water or reversed osmosis purified water, delivered by iontophoresis to skin.
Total duration of treatment: single treatment only
Total duration of follow-up: one hour after study completion
2. 4% sodium cromoglicate cutaneous emulsion or vehicle, applied topically to skin
Total duration of treatment: three days of treatment before study day

Total duration of follow-up: one hour after last treatment
3. 1%, 2% 4% sodium cromoglicate cutaneous emulsion or vehicle, applied topically to skin
Total duration of treatment: three days of treatment before study day
Total duration of follow-up: one hour after last treatment

All subjects challenged with intrademal histamine, 20 microlitres of 1 micromolar.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Sodium cromoglicate

Primary outcome measure
1. Change in severity of itch measured every 20 seconds for 5 minutes after injection of histamine using 100 mm Visual Analogue Scale
2. Change in area of flare and blood flux using scanning laser Doppler imaging
3. Change in area of weal using planimetry

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/04/2000

Completion date
01/08/2000

Eligibility

Key inclusion criteria
1. Healthy adult volunteers (18 - 65 years old), male only
2. Recruited from the staff and students of Southampton University Medical School and Southampton General Hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16 to 20 subjects per part (three parts)

Key exclusion criteria
1. Pregnancy
2. Presence of skin disease
3. Taking of drugs which may interfere with the study, including corticosteroids, antihistamines, antidepressants and psychotropic drugs

Date of first enrolment
01/04/2000

Date of final enrolment
01/08/2000

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dermatopharmacology Unit
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Hewlett Healthcare Ltd (UK)

Sponsor details
No.1 Mill, The Wharf
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Hewlett Healthcare Ltd (UK)

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?
Results article	results	01/02/2001		Yes	No
Results article	results	01/03/2004		Yes	No