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

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

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

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

Study type(s)

Treatment

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(s)

- 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

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

Study participating centre
Dermatopharmacology Unit
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation

Hewlett Healthcare Ltd (UK)

Funder(s)

Funder type

Industry

Funder Name

Hewlett Healthcare Ltd (UK)

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	01/02/2001	Yes	No
Results article	results	01/03/2004	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes