

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

<b>Submission date</b> 02/09/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2010	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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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 intradermal 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

England

**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?
<a href="#">Results article</a>	results	01/02/2001		Yes	No
<a href="#">Results article</a>	results	01/03/2004		Yes	No