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Study of the Safety and Efficacy of an Iontophoretic Device to Treat Recurrent Herpes Labialis

Submission date	Recruitment status	[_] Prospectively registered
14/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2005	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
18/08/2011	Infections and Infestations	[_] 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
COMIRB Protocol 02-925

Study information

Scientific Title

Study objectives
To determine the tolerability, safety, and efficacy of an iontophoretic device (ID) that will deliver silver ions to the skin at the site of impending or established recurrent oral herpes simplex virus (HSV) versus the modified control device.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Recurrent herpes

Interventions
In this study, 13 subjects with a history of herpes labialis used both a test and a placebo device in two separate episodes in order to treat HSV lesions. The stages of the lesions were frequently assessed by the clinician and the subjects. Additionally, the subjects assessed their pain levels. The data were analysed using a paired t-test.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure

Reduction in the time until the cessation of pain and reduction in the time until healed lesion healed.

Secondary outcome measures
Not provided at time of registration

Overall study start date
22/07/2003

Completion date
27/07/2004

Eligibility

Key inclusion criteria
1. Age 18 years or greater
2. Peri-oral HSV occurring four or more times per year

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
13

Key exclusion criteria
1. No serious medical illness
2. No use of systemic immunosuppressive therapy
3. No significant dermatological illness on the face
4. No known allergy to metal ions or components of the electrolyte ointment
5. No antiviral therapy in the 7 days prior to an outbreak and during the outbreak
6. Must forego other treatments for HSV during an outbreak
7. Must forego use of lipstick or other emollients to cover a peri-oral HSV lesion

Date of first enrolment
22/07/2003

Date of final enrolment
27/07/2004

Locations

Countries of recruitment
United States of America

Study participating centre
Klearsen Corporation
Boulder
United States of America
CO 80303

Sponsor information

Organisation
Klearsen Corporation (USA)

Sponsor details
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Sponsor type
Industry

Website
http://www.klearsen.com/index.html

Funder(s)

Funder type
Industry

Funder Name
Klearsen Corporation (USA)

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