

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

Submission date
14/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
29/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
18/08/2011

Condition category
Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Steven R Frank

Contact details

Klearsen Corporation
Research Department
3125 Sterling Circle
Boulder
United States of America
CO 80303

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

3125 Sterling Circle

Boulder

United States of America

CO 80303

+1 303-443-8700

info@klearsen.com

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