

Evaluation of the efficacy and safety of a Sheabutter extract on cold sores (herpes simplex labialis)

Submission date 05/05/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 05/07/2005	Overall study status Completed	☐ Protocol
Last Edited 31/03/2010	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☐ Results
		☐ 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

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Contact details

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Additional identifiers

Protocol serial number

BPCS01

Study information

Scientific Title

Study objectives

The hypothesis is that various concentrations of Sheabutter extract BSP110 are able to reduce the healing time of cold sores and prevent their recurrence in participants with 6 or more self reported cold sores a year.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Herpes Simplex Labialis

Interventions

Acute study - 100% sheabutter extract BSP 110 ointment versus placebo of yellow petrolatum.

Maintenance study - 25% sheabutter lip balm versus 25% yellow petrolatum lip balm.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sheabutter extract

Primary outcome(s)

Acute study: Duration of initial herpes labialis episode.

Maintenance study: Number of herpes labialis episodes during the 6 months of the maintenance study period.

Key secondary outcome(s)

Acute study:

1. Investigator-assessment of Herpes Lesion development stage
2. Participant self-assessment of severity of symptoms including pain, tingling, itching, swelling, blistering, oozing and crusting using Likert scales (0 = none, 1 = mild, 2 = moderate, 3 = severe)
3. Quality of Life measured by Short Form-36 questionnaire and the Dermatology Life Quality Index

Maintenance study:

1. The number of participants who develop lesions during the 6 months of the maintenance

study period

2. Time to first herpes episode

3. Duration of lesions

4. Use of rescue medication

5. Participant self-assessment of severity of symptoms including pain, tingling, itching, swelling, blistering, oozing and crusting using Likert scales (0 = none, 1 = mild, 2 = moderate, 3 = severe)

6. Quality of Life measured by Short Form-36 questionnaire and the Dermatology Life Quality Index

Completion date

31/03/2006

Eligibility

Key inclusion criteria

Subjects aged 18 and 75 years, in good general health who have a clinical history of recurrent herpes labialis, with at least six self reported episodes of herpes lesion in the past year and at least one recurrence every three months.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. History of immunodeficiency

2. Use of other antiviral agents (including herbal medications), anti-inflammatory medications, steroids or analgesics during the treatment period

3. Known allergy to Sheabutter

4. Liver function tests greater than 3 times the upper limit of normal at baseline

5. Female participants who are lactating, pregnant or planning to become pregnant

6. Participants who have participated in another clinical trial in the last 30 days

7. Participants unwilling to comply with the study protocol

8. Any other condition, which in the opinion of the investigators could compromise the study

Date of first enrolment

01/02/2005

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

Australia

Study participating centre

Mater Health Services

South Brisbane

Australia

4101

Sponsor information

Organisation

BSP Pharma A/S (Denmark)

ROR

<https://ror.org/05tzrdd39>

Funder(s)

Funder type

Industry

Funder Name

BSP Pharma A/S (Denmark) - AUD478,790

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration