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

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

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

Study design
Randomised controlled trial

Primary study design
Interventional

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 recurrance 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