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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### 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 measure

Acute study: Duration of initial herpes labialis episode.
Maintenance study: Number of herpes labialis episodes during the 6 months of the maintenance study period.

### Secondary outcome measures
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

### Overall study start date
01/02/2005

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
160

### 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)

### Sponsor details
M.P Bruuns Gade 27
Aarhus
Denmark
DK-8000

### Sponsor type
Industry

### ROR
https://ror.org/05tzrdd39

# Funder(s)

**Funder type**
Industry

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

# 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