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Randomised placebo controlled trial on the safety and efficacy of a topical treatment for bilaternal chronic plaque psoriasis in adults

Submission date 16/06/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 21/09/2005	**Overall study status** Completed	
Last Edited 14/09/2009	**Condition category** Skin and Connective Tissue Diseases	

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
BJPS01

Study information

Scientific Title

Study objectives
H BioJuven SBS1 Herbal Skin Balm is able to reduce the severity of chronic plaque psoriasis in adults.

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
Mild to moderate bilaternal chronic plaque psoriasis

Interventions
H BioJuven SBS1 Herbal Skin Balm versus an indentical placebo skin balm.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
H BioJuven SBS1 Herbal Skin Balm

Primary outcome measure

The change in erythema, scaling and induration (ESI) scores from beginning to end of treatment. Erythema (redness), scaling and induration (thickening), is scored on a 0 to 3 scale (0 = none and 3 = severe) and sum of these scores for each target lesion is the ESI score.

Secondary outcome measures
1. Quality of life will be measured using the Dermatology Life Quality Index (DLQI)
2. Investigator and patient ratings of the efficacy of the treatment which measured on a 6 point scale: worse; unchanged; slight improvement (25%); moderate improvement (50%); marked improvement (75%); or clearance

Overall study start date
27/06/2005

Completion date
20/12/2005

Eligibility

Key inclusion criteria
1. Participants with mild to moderate, bilateral symmetric, chronic plaque type psoriasis
2. In good general health and adequate venous access
3. Participants of childbearing age who agree to continue using birth control measures for the duration of the study
4. Males and Females between 18 and 75 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
29

Key exclusion criteria
1. Chronic plaque psoriasis involving more than 60% of the body surface
2. Pustular or generalized erythrodermic psoriasis
3. Use of medications which affect psoriasis during the study (e.g. systemic therapy including retinoids, methotrexate, cyclosporine, or corticosteroid and non corticosteroid topical therapy, including vitamin D analogues, tazarotene, tacrolimus)
4. Systemic therapy for psoriasis within 30 days of baseline
5. UV light therapy within 21 days of baseline
6. Topical corticosteroids within 14 days of baseline

7. Liver function tests greater than 3 times the upper limit of normal at baseline
8. Female participants who are lactating, pregnant or planning to become pregnant
9. Participants have participated in another clinical trial in the last 30 days
10. Participants unwilling to comply with study protocol
11. Any other condition, which in the opinion of the investigators could compromise the study

Date of first enrolment
27/06/2005

Date of final enrolment
20/12/2005

Locations

Countries of recruitment
Australia

Study participating centre
39 Annerley Rd
Brisbane
Australia
4101

Sponsor information

Organisation
H BioJuven Pty Ltd (Australia)

Sponsor details
36-38 Gipps St
Collingwood
Melbourne
Australia
3066

Sponsor type
Industry

Website
http://www.swisse.com.au

Funder(s)

Funder type
Industry

Funder Name
H BioJuven Pty Ltd (Australia)

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