

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

Submission date
16/06/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
14/09/2009

Condition category
Skin and Connective Tissue Diseases

☐ 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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Australia
4101

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mild to moderate bilateral chronic plaque psoriasis

Interventions

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

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

H BioJuven SBS1 Herbal Skin Balm

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

Funder(s)

Funder type
Industry

Funder Name
H BioJuven Pty Ltd (Australia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration