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Randomised, observer-blinded, vehicle-controlled trial on the efficacy and safety of a topical indigo naturalis ointment treatment for recalcitrant psoriasis vulgaris

Submission date
01/01/2006

Recruitment status
No longer recruiting

Registration date
01/03/2006

Overall study status
Completed

Last Edited
08/09/2011

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Yin-ku Lin

Contact details
123 Ding-Hu road
Kuei-Shan
Taoyuan
Taiwan
333
lin1266@adm.cgmh.org.tw

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CMRPG 33024

Study information

Scientific Title

Study objectives
The topical indigo naturalis ointment is effective for the treatment of recalcitrant psoriasis vulgaris.

Please note that as of 10/04/2007 the trial study design was changed to:
Randomised, observer-blinded, placebo-controlled, intra-patient comparison.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study protocol was approved by the Institutional Review Board of the Chang Gung Memorial Hospital (ref: CGMH IRB No. 93- 129B).

Study design
Randomised, double-blind, placebo-controlled, intra-patient comparison

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Recalcitrant chronic plaque psoriasis

Interventions
Forty patients with recalcitrant psoriasis vulgaris were treated with indigo naturalis ointment and ointment vehicles were applied daily to either of two bilaterally symmetrical plaques for 12 weeks. Every two weeks, the investigators evaluate the treated plaques. (As of 10/04/07 the following sentence should be disregarded: the patients and investigators were blinded as to the content of the two bottles).

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Indigo naturalis ointment

Primary outcome measure
Clinical and laboratory assessments were done at baseline and every two weeks thereafter until 12 weeks after the start therapy. The changes in Erythema, Scaling, Indurations (ESI) and and bilateral plaque areas are recorded from the beginning to end of the treatments. Erythema (redness), scaling and indurations (thickening), are scored on a 0 to 8 scale (where 0 = none and 8 = very severe); the sum of these scores for each target lesion is the ESI score. The bilateral plaque area is rated from of 0% to 100% (0% = clearance and 100% = baseline).

Secondary outcome measures
Investigators will take biopsies from each treated lesion and analysis the immunohistochemical stains for markers of proliferation, differentiation and inflammation at the end of treatment.

Overall study start date
01/05/2004

Completion date
30/04/2005

Eligibility

Key inclusion criteria
1. Participants with bilateral symmetric, chronic plaque-type psoriasis
2. Participants who have a history of plaque psoriasis for a minimum of two years
3. Participants who have a history of resistance to at least two topical treatments (e.g. corticosteroid and vitamin D3 analogues)
4. Participants who have good general health and normal full blood picture, renal, and liver function in tests done before starting the study
5. Participants of childbearing age who agree to continue using birth control measures for the duration of the study
6. Males and females between 18 and 75 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex

Both

Target number of participants
40

Key exclusion criteria
1. Chronic plaque psoriasis involving more than 60% of the body surface
2. Pustular or generalised 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. Ultra-Violet (UV) light therapy within 21 days of baseline
6. Topical therapy within 14 days of baseline
7. Participants that test positive for Human Immunodeficiency Virus (HIV), hepatitis B surface antigen, or hepatitis C
8. Participants that have a current history of alcohol or drug abuse
9. Participants that have a history of hepatitis
10. Participants that have a clinically significant laboratory abnormality
11. Participants that have a history of sensitivity to Chinese herbs, olive oil, yellow wax and Vaseline
12. Female participants who are lactating, pregnant or planning to become pregnant
13. Participants that have participated in another clinical trial in the last 30 days
14. Participants who are unwilling to comply with study protocol
15. Any other conditions, which in the opinion of the investigators could compromise the study

Date of first enrolment
01/05/2004

Date of final enrolment
30/04/2005

Locations

Countries of recruitment
Taiwan

Study participating centre
123 Ding-Hu road
Taoyuan
Taiwan
333

Sponsor information

Organisation

Chang Gung Memorial Hospital (Taiwan)

Sponsor details
123 Ding-Hu road
Kuei-Shan
Taoyuan
Taiwan
333
lin1266@adm.cgmh.org.tw

Sponsor type
Hospital/treatment centre

Website
http://www.cgmh.org.tw

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Chang Gung Memorial Hospital (Taiwan) (ref: CMRPG 33024)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2008		Yes	No