

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

<b>Submission date</b> 01/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/03/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/09/2011	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## 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

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**Sponsor information**

**Organisation**

Chang Gung Memorial Hospital (Taiwan)

**Sponsor details**

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**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?
<a href="#">Results article</a>	results	01/11/2008		Yes	No