

Comparison of efficacy and safety of Betesil® medicated plaster versus Daivobet®/Dovobet® ointment in the treatment of chronic plaque psoriasis

Submission date 14/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/08/2011	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

2009-016969-28 / 09EU_BMT12

Study information

Scientific Title

Multicentre, prospective, assessor-blind, in parallel groups randomised and controlled trial of the efficacy and safety of betamethasone valerate 2.25mg medicated plaster (Betesil®) versus 50µg-0,5mg/g calcipotriol-betamethasone (dipropionate) ointment (Daivobet®/Dovobet®), in the treatment of chronic plaque psoriasis

Study objectives

The primary aim of the study is to evaluate the efficacy of Betesil® (IBSA-Institut Biochimique S. A.) medicated plaster as compared to the reference drug, Daivobet®/Dovobet® (LEO Pharmaceutical Products), when applied daily during a period of maximum 4 weeks on psoriasis plaques localised at elbows and knees.

Secondary aims are the evaluation of the products safety and the record of subjects acceptability of the treatments.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Bioethics Commission at the Regional Medical Chamber in Krakow (Komisja Bioetyczna przy Okręgowej Izbie Lekarskiej w Krakowie) (Coordinating Centre in Poland) approved on the 13th of January 2010 (ref: 1/KBL/OIL/2010)
2. Ethical Committee of the University of Rome "Tor Vergata" (Coordinating Centre in Italy) approved on the 16th of December 2009 (ref: 99/09P.U)
3. Committee for Protection of Research Subjects (Comité de Protection des Personnes [CPP]) Sud Mediterranee V of Nice (Coordinating Centre in France) approved on the 5th of December 2010 (ref 10.003)

Study design

Interventional phase IV prospective randomised assessor blind vs. reference-marketed product controlled multicentre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information sheet may be found at http://www.betesil.co.uk/patient/betesil_PIL.pdf

Health condition(s) or problem(s) studied

Chronic plaque psoriasis

Interventions

Patients will be randomised to receive either

1. Betamethasone valerate 2.25mg medicated plaster (Betesil®, IBSA-Institut Biochimique S.A.): once daily for maximum 4 weeks
2. 50µg-0,5mg/g calcipotriol-betamethasone (dipropionate) ointment (Daivobet®/Dovobet®, LEO Pharmaceutical Products): once daily for maximum 4 weeks

Intervention Type

Other

Phase

Phase IV

Primary outcome measure

Total Severity Score (TSS - erythema, scaling, elevation, pruritus) as evaluated by the Blind Assessor at the end of the 4-weeks treatment period.

Secondary outcome measures

1. TSS assessed by the Blind Assessor at week 1, 2 and 3;
2. Individual symptoms sub-scores (erythema, scaling, elevation, pruritus) of TSS assessed by the Blind Assessor at week 1, 2, 3 and 4
3. Physician's Global Assessment (PGA) score assessed by the Blind Assessor at week 1, 2, 3 and 4
4. Number of cleared subjects after 4 weeks of treatment (i.e., TSS ≤1), as evaluated by the independent experienced dermatologist judging on standardised photographs
5. Surface area of the target plaques at weeks 1, 2, 3 and 4, based on the analysis of the standardised photographs
6. Subjects evaluation of Quality of Life (QoL) by Dermatology Life Quality Index (DLQI) at baseline and at weeks 1, 2, 3 and 4
7. Subjects weekly self-assessment of global improvement by PGA score
8. Evaluation of global subjects treatment satisfaction and acceptability
9. Rate of - and time to - rebound/relapse during the follow-up period
10. Number of subjects reporting adverse events (AEs)
11. AEs characteristics and frequency

Overall study start date

01/04/2010

Completion date

31/12/2010

Eligibility

Key inclusion criteria

1. Out-patients of either sex
2. Aged 18 years or more
3. With diagnosis of mild-to-moderate (Total Severity Score [TSS] ≥ 4, as judged by the Investigator), stable, chronic plaque psoriasis, for at least 12 months
4. Involving less than 10% of the body surface area (BSA) (1 hand representing approximately 1% of BSA) (i.e. mild-to-moderate psoriasis according to CHMP/EWP/2454/02corr19)
5. Not requiring systemic treatment

6. With at least 2 bilateral plaques in extensory part of limbs, i.e. knees and/or elbows, >10 cm² and <75 cm² (surface area equivalent of one BMV medicated plasters)
7. Subjects must be able to comprehend the full nature and purpose of the study, including possible risks and side effects, ability to co-operate with the Investigator, to comply with the requirements of the entire study and to return for the required examinations
8. Subjects must sign a written informed consent to the participation prior to inclusion in the study
9. For France only: Subjects covered by an insurance policy

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Female subjects of childbearing potential (i.e., not status post hysterectomy or tubal ligation) not using an appropriate method of contraception according to the definition of Note 3 of ICH M3 Guideline
2. Pregnant or lactating women
3. Subjects who have guttate, pustular or other non-plaque form of psoriasis
4. Subjects only presenting with lesions on the scalp, face or intertriginous areas, not suitable for treatment with a topical adhesive plaster
5. Subjects only presenting lesions <10 cm² or >75 cm²
6. Subjects with more severe stage of chronic plaque psoriasis presenting target lesions with one of the clinical signs or symptoms having a score of 0 (i.e. TSS total score <4)
7. Subjects needing a systemic therapeutic approach in order to control the disease
8. Subjects having used topical anti-psoriatic drugs during the 2 weeks before inclusion in this study
9. Or having received topical retinoids for psoriasis within 4 weeks before inclusion
10. Or having received any systemic anti-psoriatic therapy (including intralesional corticosteroid, vitamin D in high doses, vitamin D analogues, methotrexate, cyclosporine, UVB programs or UVA /psoralen programs) within 4 weeks before inclusion
11. Or having received any biological therapies targeting the immune responses involved in the pathogenesis of psoriasis within 1 year before inclusion
12. Or having used any bland emollient on areas to be treated during the 48 hours preceding inclusion
13. Subjects with ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients
14. Subjects with history of anaphylaxis to drugs or allergic reactions in general, which the Investigator considers may affect the outcome of the study
15. Subjects with other dermatological conditions that could interfere with the assessment of

the psoriatic lesions, according to the investigators opinion

16. Subjects with any underlying disease or medication that severely compromise the subject's immune system;

17. Subjects in treatment with lithium or hydroxychloroquine (Plaquenil®)

18. Subjects on a chronic, stable regimen of β -blocker therapy may be included, but the dosage should not be modified for the whole duration of the study

19. Subjects suffering from severe systemic diseases (e.g. cancer, severe acute infection)

20. Subjects with severe cardiac, renal or hepatic impairment

21. Subjects suffering from psychiatric diseases, not allowing the observance of the protocol; history of current alcohol or drug abuse dated < 1 year

22. Subjects enrolled in the evaluation of any experimental drug or in any other type of clinical investigation concurrently or during 3 months before entering this study

23. Subjects previously enrolled in this study

24. Subjects not amenable to topical treatment

25. Subjects not able to understand the purposes of the study

26. Subjects refusing to give a written informed consent or unable to give a valid informed consent

27. Subjects deprived of their freedom by administrative or legal decision, or being the subject of a legal protection measure, or out of state to express their consent

28. Subjects not reliable, according to the investigators opinion

Date of first enrolment

01/04/2010

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

France

Italy

Poland

Study participating centre

Service de Dermatologie, Hôpital de l'Archet 2

NICE Cedex 3

France

06202

Sponsor information

Organisation

Institut Biochimique SA (IBSA) (Switzerland)

Sponsor details

Via del Piano
Pambio-Noranco
Switzerland
6915

Sponsor type

Industry

ROR

<https://ror.org/051tj3a26>

Funder(s)**Funder type**

Industry

Funder Name

Institut Biochimique SA (IBSA) (Switzerland) (ref: 09EU_BMT12)

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