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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

Registration date
17/06/2010

Last Edited
11/08/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Skin and Connective Tissue Diseases

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

Protocol serial number
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 13the 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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 -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 lArchet 2
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Sponsor information

Organisation
Institut Biochimique SA (IBSA) (Switzerland)

ROR
https://ror.org/051tj3a26

Funder(s)

Funder type
Industry

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

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes