ISRCTN68864186 https://doi.org/10.1186/ISRCTN68864186

Efficacy and safety of Institut Biochimique SA (IBSA) 0.1% betamethasone valerate (BMV) medicated plaster versus reference marketed product for the treatment of chronic plaque psoriasis

Submission date	Recruitment status
12/08/2009	No longer recruiting
Registration date	**Overall study status**
11/02/2010	Completed
Last Edited	**Condition category**
19/05/2022	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 Luigi Naldi

Contact details
Centro GISED
U.O. Dermatologica
Ospedali Riuniti Di Bergamo
L.go Barozzi, 1
Bergamo
Italy
24100
-
luigi.naldi@gised.it

Additional identifiers

Clinical Trials Information System (CTIS)
2005-003050-96

Protocol serial number
04EU/BMT06; EudraCT No.:

Study information

Scientific Title
Multicentre, prospective, assessor-blind, in parallel groups randomised and versus reference marketed product controlled confirmatory trial of the efficacy and safety of Institut Biochimique SA (IBSA) 0.1% betamethasone valerate (BMV) medicated plaster for the treatment of chronic plaque psoriasis

Study objectives
To ascertain if Institut Biochimique SA (IBSA) 0.1% betamethasone valerate (BMV) medicated plaster is significantly more effective as compared to the reference marketed BMV 0.1% cream for the treatment of chronic plaque psoriasis, when applied daily during a period of 3 to 5 weeks (superiority design).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Comitato di Bioetica dell'Azienda Ospedali Riuniti di Bergamo) approved on the 30th November 2005 (ref: 1681)

Study design
Phase III prospective randomised assessor-blind controlled multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild to moderate chronic plaque psoriasis

Interventions
Test drug:
IBSA BMV medicated plaster, is a 75 cm^2 plaster containing 2.25 mg of BMV as active ingredient (= 0.03 mg/cm^2); plaster administered topically on the target lesions once a day (morning), and worn for not less than 20 consecutive hours. A minimum of two and a maximum of eight plasters, based on number and extension of plaques identified as target areas.

Comparator product:
Betneval® 0.1% cream (GlaxoSmithKline), supplied as 30 g cream tubes. Differently from the plasters, cream will be applied twice a day on the target lesions, morning and evening. An adequate amount of cream, based on number and extension of the plaques identified as target areas, The products application will be repeated daily during 3 or 5 consecutive weeks, according to the treatment outcome.

Patients will be required to concomitantly treat non-target plaques only with a bland emollient (urea 5%) during the same period.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
0.1% betamethasone valerate (BMV) medicated plaster, reference marketed product

Primary outcome(s)
Number of patients showing remission (i.e. the disappearance of the active lesions of the skin areas identified as target areas) after 3 weeks of treatment, based on the Psoriasis Global Assessment (PGA) score as independently evaluated by two blind assessors based on digitalised images.

Key secondary outcome(s))
1. Number (%) of patients with remission after 3 weeks of treatment as assessed by the principal Investigator at each centre and by the patient
2. Number (%) of patients with remission after 5 weeks of treatment as assessed by the blind assessors, the principal Investigator at each centre and the patient
3. Changes from baseline of total extension of target lesions, as measured by an independent blind operator, after 3 and 5 weeks of treatment
4. Changes from baseline in PGA score assessed at each visit (week 3 and week 5) by the blind assessors, the principal Investigator at each centre and the patient
5. Patient's self-assessment of symptoms severity (itching, soreness) by means of a 10-point severity categorical scale (from 0 = no symptoms, to 10 = very severe symptoms), after 3 and 5 weeks of treatment
6. Patient's assessment of treatment acceptability/satisfaction, by means of a 10-point categorical scale (from 0 = very poor, to 10 = excellent), at the end of the treatment period (either week 3 or week 5)
7. Patient's assessment of ease of use by means of a 10-point categorical scale (from 0 = very poor, to 10 = excellent), at the end of the treatment period (either week 3 or week 5)
8. Number (%) of patients (among those having reached a complete remission at the end of treatment) showing patent relapse of the disease, and number (%) of patients showing disease rebound after treatment interruption
9. Time to relapse and/or rebound
10. Safety:
10.1. General adverse events (AEs)
10.2. Patient's assessment of treatment local tolerability, by means of a 10-point categorical scale (from 0 = very poor, to 10 = excellent), at the end of the treatment period (either week 3 or week 5)

Completion date
11/06/2008

Eligibility

Key inclusion criteria

1. Subjects (outpatients) of both genders
2. Aged 18 years or more
3. Suffering from stable chronic plaque psoriasis (psoriasis vulgaris), involving less than 10% of the body surface area (BSA) (i.e. mild to moderate psoriasis according to CHMP/EWP/2454 /02corr19) and presenting with psoriatic plaques in extensory skin areas, i.e. elbow and/or knee
4. Have at least two plaques on extensory parts of limbs that must be each greater than or equal to 10 cm^2 but less than 150 cm^2 (surface area equivalent of two BMV medicated plasters). These plaques, defined as target areas, will be treated with the tested formulation, BMV medicated plaster, or with the comparator product, BMV 0.1% cream (not occluded), according to a computer generated, fully randomised sequence. When present, other affected skin areas, different from those identified as target plaques, will be treated only with a bland emollient (5% urea) during the whole treatment period.
5. Female subjects of childbearing potential (i.e., not status post hysterectomy or tubal ligation) must use an appropriate method of contraception according to the definition of Note 3 of ICH M3 Guideline; pregnant or breast-feeding women will not be included
6. Ability to comprehend the full nature and purpose of the study, including possible risks and side effects
7. Ability to cooperate with the Investigator and to comply with the requirements of the entire study
8. Signed written informed consent prior to inclusion in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Guttate, pustular or other non-plaque form of psoriasis
2. More severe stage of chronic plaque psoriasis, needing a systemic therapeutic approach in order to control the disease and not amenable to topical treatment
3. No concurrent dermatological conditions that could interfere with the assessment of the psoriatic lesion
4. No underlying disease or medication that severely compromise the patient's immune system
5. No history of anaphylaxis to drugs or allergic reactions in general, which the Investigator considers to potentially affect the outcome of the study
6. No use of topical anti-psoriatic drugs during the two weeks before inclusion in this study
7. No use of a topical retinoids during the 4 weeks before inclusion in this study
8. No systemic antipsoriatic therapy (e.g. corticosteroids - including intralesional corticosteroid, vitamin D in high doses, vitamin D analogs, methotrexate, cyclosporin, UVB programs or UVA

/psoralen programs) within 4 weeks before inclusion
9. No participation in the evaluation of any investigational drug during 3 months before the study

Date of first enrolment
11/04/2006

Date of final enrolment
11/06/2008

Locations

Countries of recruitment
France

Italy

Poland

Switzerland

Study participating centre
Centro GISED
Bergamo
Italy
24100

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)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		20/04/2022	19/05/2022	No	No