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Evaluation of DEAT0217 versus standard of care to compare effectiveness and safety in treating moderate psoriasis in adult patients

Submission date
25/11/2021

Recruitment status
No longer recruiting

Registration date
16/12/2021

Overall study status
Completed

Last Edited
26/11/2021

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

Background and Study Aims
Psoriasis is a skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. These patches normally appear on your elbows, knees, scalp, and lower back, but can appear anywhere on your body. Most people are only affected with small patches. In some cases, the patches can be itchy or sore.

This is a prospective, multicenter, open-label study for evaluation of efficacy and safety of a new device (DEAT0217) versus the standard of care (e.g calcipotriol) in adult patients diagnosed with mild to moderate psoriasis.

Who can participate?
Adult subjects 18 years or older diagnosed with mild to moderate plaque psoriasis.

What does the study involve?
Participants will be randomly allocated to receive DEAT0217 applied twice a day for 4 weeks, or the standard of care.

What are the possible benefits and risks of participating?
Benefits:
This treatment could be very useful for you in the treatment of mild to moderate psoriasis, by reducing the symptoms associated with this diagnosis and improving the quality of life. Study treatment may bring you personal benefits, or it may not. Even if there are no benefits for you, the results of this study could help discover new treatments that reduce the symptoms of this condition.
Your participation in this study is voluntary.
If, according to the treatment plan, the expected results are not obtained, your doctor will decide whether or not to continue the treatment.
Risks:
You are not required to participate in this study, and your study doctor will tell you about other treatments and their risks and benefits. The treatment strategy for your condition will be

recommended to you by your doctor. Thus, your doctor may prescribe an alternative to study treatment.

Where is the study run from?
Devintec SAGL (Switzerland)

When is the study starting and how long is it expected to run for?
May 2020 to November 2020

Who is funding the study?
Devintec SAGL, Lugano, Switzerland

Who is the main contact?
Alina Iordache
alina.iordache@cebis-int.com

Contact information

Type(s)
Scientific

Contact name
Mrs Alina Iordache

ORCID ID
https://orcid.org/0000-0002-5931-0463

Contact details
222 Calea Plevnei 3rd Floor
Bucharest
Romania
060016
+40 737 640 721
alina.iordache@cebis-int.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
CEBDEV-04032020

Study information

Scientific Title
A prospective, multicenter, open-label study to evaluate the safety and efficacy of DE-AT0217 versus standard of care (e.g. calcipotriol) in adult patients diagnosed with mild to moderate psoriasis

Acronym
CLEAR Study

Study objectives
This is a prospective, multicenter, open-label study for evaluation of efficacy and safety of DEAT0217 versus standard of care (e.g calcipotriol) in adult patients diagnosed with mild to moderate psoriasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2020, National Committee of Medical Bioethics for clinical trials (Stefan Cel Mare 19-21 Road, District 2, Bucharest, Romania; +40 (0)212102880; comisia.bioetica@adsm.ro.), ref: CPMP/ICH/135/95; ICH Topic E6

Study design
Interventional multi center open label randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult patients diagnosed with mild to moderate psoriasis.

Interventions
The primary objective is to assess the clinical efficacy of the DE-AT0217 in relieving the symptomatology of mild to moderate psoriasis.

The investigational medical device will be administered to the subjects who meet the eligibility criteria and give their informed consent to participate in the study. The treatment with DE-AT0217 will be administered by topical route, according to the approved leaflet.

The treatment will be administered according to the approved leaflet for 29 consecutive days;

Visits:
Visit 1 (Day 0- Screening visit)
Visit 2- Day 15 (after 14 days of treatment)
Visit 3 - Day 29 (after 14 days of treatment)
Visit 4 – Day 43 (after 14 days from the end of the treatment)

Each investigator was asked to enroll the subjects in a 1:1 ratio to avoid systematic errors that could occur during group assignment or due to subjectivity.

Intervention Type
Device

Phase

Phase III

Drug/device/biological/vaccine name(s)
DE-AT0217

Primary outcome(s)
Efficacy is the primary measure. It will be evaluated from baseline to day 29 in terms of:
1. Erythema, Induration/Thickness, Scaling measured using PASI50
2. How much the skin problem has affected patient's life over the last week measured using the Dermatology Life Quality Index (DLQI)
3. Degree of erythema, induration, scale, averaged over the entire body measured using the sPGA
4. Itch measured using VAS on a scale of "no itch" (left) to "worst imaginable itch" (right)

The criteria for efficacy evaluation will be the comparison of symptomatology reduction based, on clinical observations (PASI, DLQI, PGI and VAS scores), between baseline and 4th Visit.
The criteria for safety evaluation will be the frequency of AEs occurrence, the number of drop-outs due to side effects and the disease progression.

Key secondary outcome(s))
Safety measured using patient records throughout the study:
1. Percentage of participants who experienced an AE
2. Number of drop-out due to side effects
3. Disease progression

Completion date
11/11/2020

Eligibility

Key inclusion criteria
1. Adult subjects 18 years or older
2. Subjects willing to sign the informed consent
3. Subjects previously diagnosed with mild to moderate plaque psoriasis
4. Subjects willing and able to comply with all clinic visits and study-related procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Use of systemic and topical anti psoriatic therapy on the areas within 2 weeks prior to the beginning of the study
2. Concomitant use of systemic anti psoriatic therapy (e.g. methotrexate, biologics, phototherapy)
3. Concomitant use of topical corticotherapy
3. Any dermatological disease that might interfere psoriasis clinical evaluation or bring the subject in danger, or have other serious dermatological disease other than psoriasis
4. Pregnant or breast-feeding women or women planning to become pregnant or breastfeed during the study.
5. Hypersensitivity or allergy to any of the IMP ingredients

Date of first enrolment
24/06/2020

Date of final enrolment
28/09/2020

Locations

Countries of recruitment
Romania

Study participating centre
Emergency County Hospital
Tudor Vladimirescu, 48.
Targoviste
Romania
130095

Study participating centre
Individual Medical Office of Dermatology Prof. Dr. Orasan Remus Ioan
Bulevardul 21 Decembrie 1989 23
Cluj
Romania
400000

Study participating centre
Colentina Clinical Hospital
Șoseaua Ștefan cel Mare 19-21

Bucharest
Romania
020125

Sponsor information

Organisation
Devintec SAGL

Funder(s)

Funder type
Industry

Funder Name
Devintec SAGL

Results and Publications

Individual participant data (IPD) sharing plan
The data will be collected under the study confidentiality and for the study purpose only, according to the approved informed consent form. The study data will be archived according to the sponsor requirements and local regulatory requirements.

The datasets generated during and/or analysed during the current study are available from the corresponding authors on reasonable request:
Rosca Valentina, Emergency County Hospital
Orasan Remus. Individual Medical Office of Dermatology Prof. Dr. Orasan Remus Ioan
Magda Constantin, Colentina Clinical Hospital

IPD sharing plan summary
Available on request