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Evaluation of Dermasectan® versus SoC to compare efficacy and safety in treating atopic eczema (dermatitis) in adults

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
24/11/2021

Overall study status
Completed

Last Edited
11/08/2023

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
Atopic dermatitis (AD) is a long-term disease, that often appears during early childhood and often before the age of two. It is estimated that about 10% of patients continue to suffer from eczema as adults. It has been shown in recent studies that the disease is more likely to occur in women and during the third decade of life and is prevalently localized in the limb flexures, eyelids, and perioral region, but also forehead, cheeks, anterolateral region of the neck. The diagnosis of AD is based on the following constellation of clinical findings: pruritus, facial and extensor eczema in infants and children, flexural eczema in adults, and chronicity of dermatitis. Atopic dermatitis in adults is often a serious condition, so the diagnosis must be precise. If the disease dates back to childhood, and/or is combined with atopic respiratory symptoms (allergic rhinitis, allergic dermatitis, and asthma), and/or even digestive allergies, and there are typical clinical signs, like chronic thick, lichenified eczema, with oozing flare-ups; the diagnosis can be considered definitive. Besides childhood persistence, another cause for atopic dermatitis in adults can be a relapse by a modification of the environment (stress, cutaneous irritation, contact allergy). These patients show increased serum IgE levels (>150kU/L).

The aim of the study is to assess the clinical efficacy of Dermasectan® in alleviating the symptomatology of Atopic Dermatitis.

Who can participate?
Adult subjects, 18 years or older with AD diagnosed at screening visit.

What does the study involve?
The study lasted for 28 days, with two applications/day for 14 consecutive days of treatment with one of the study products: Dermasectan® or Placebo (depending on randomization arm).

What are the possible benefits and risks of participating?
This treatment could be very useful for you in treating atopic dermatitis by reducing the symptoms associated with this diagnosis. Even if there are no benefits for you, the results of this study could help in discovering new treatments for atopic dermatitis.

Your participation in this study is voluntary.
If by following the treatment plan, no results are obtained, your doctor will decide whether or not you should continue the treatment.
There is no information regarding risks or inconveniences.

Where is the study run from?
Novintethical Pharma SA (Switzerland)

When is the study starting and how long is it expected to run for?
June 2019 to May 2020

Who is funding the study?
Novintethical Pharma SA (Switzerland)

Who is the main contact?
Alina Iordache
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2019-001729-28

Protocol serial number
CBSNOV2301

Study information

Scientific Title

A randomized, double-blind, placebo-controlled, multicenter clinical trial investigating the efficacy and safety of Dermasectan® vs. placebo administered to adult patients with atopic dermatitis (AD)

Acronym
CONTROL

Study objectives
A double-blind, parallel, randomized, placebo-controlled, multicenter study for the evaluation of efficacy and safety of Dermasectan® vs placebo in patients diagnosed with atopic dermatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 13/06/2019, National Committee of Bioethics for Medicine and Medical Devices (Stefan Cel Mare 19-21 Road, District 2, Bucharest, Romania; +40 (0)212102880; comisia.bioetica@adsm.ro), ref: 2S/4/13.06.2019
2. Approved 17/02/2020, Ethics Committee for clinical trials (8 Damyan Gruev Str., Sofia 1303, Bulgaria; +359 (0)2 8903555; bda@bda.bg), ref: 01351/17.02.2020

Primary study design
Interventional

Study design
Double blind placebo-controlled randomized multicenter study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atopic dermatitis

Interventions
The study subjects were randomly allocated to study arm based on a computer-generated sequence with 1:1 ratio: Dermasectan or Placebo. The subjects received for 14 consecutive days two applications/day on affected areas. The medication was provided by the Study Sponsor. Each patient received the necessary amount of product for 14 days at Baseline Visit. The investigator kept the product accountability during the entire duration of the study. All subjects included in the study were diagnosed, by their doctor, with atopic dermatitis. The study lasted for 28 days, with two applications/day for 14 consecutive days of treatment with one of the study products: Dermasectan or Placebo (depending on randomization arm). Participants attend four visits: - Visit 1 – day 0 (baseline visit) - Visit 2 – day 8 (after 7 days of treatment) - Visit 3 – day 15 (After 14 days of treatment) - Visit 4 – day 28 (14 days after end of treatment) follow-up by phone

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Dermasectan®

Primary outcome(s)
1. Erythema, pruritus, exudation, excoriation, crusted erosions and lichenification are measured using a 4-point (0-3) scale - Atopic Dermatitis Severity Index (ADSI) - recorded at visits from: day 0, day 8, day 15.
2. Redness, swelling, oozing/crusting, scratch marks, skin thickening (lichenification), dryness are measured using SCORAD (Score Atopic Dermatitis) Calculator at the doctor's office at the time of the visits at day 0, day 8, day 15;
3. Patient chart assessment by PATIENT ORIENTED ECZEMA MEASURE (POEM)– recorded at visits from: day 0, day 8, day 15.

Key secondary outcome(s)
The safety outcomes (percentage of participants who experienced an AE, number of drop-out due to side effects, disease progression) were evaluated during study visit at Day 8, Day 15 and Day 28.

Completion date
02/05/2020

Eligibility

Key inclusion criteria
1. Adult subjects, 18 years or older
2. Subject willing to sign the informed consent
3. AD diagnosed at screening visit
4. Clinical digital photography to provide images of affected and healthy skin
5. Willing and able to comply with all clinic visits and study-related criteria

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. The following treatments within 4 weeks before the baseline visit, or any condition that, in the opinion of the investigator, will likely require such treatment(s) during the first 4 weeks of study treatment:
1.1 Systemic corticosteroids
1.2 Immunosuppressive/immunomodulating drugs
1.3 Phototherapy for AD
2. Treatment with certain biologics
3. Regular use (more than 2 visits per week) of a tanning booth/parlor within 4 weeks before the baseline visit
4. Planned major surgical procedure during the patient's participation in this study
5. Patient is a member of the investigational team or his/her immediate family
6. Pregnant or breast-feeding women or women planning to become pregnant or breastfeed during the study
7. Hypersensitivity to any of the ingredients of the study agents.

Date of first enrolment
13/09/2019

Date of final enrolment
04/04/2020

Locations

Countries of recruitment
Bulgaria

Romania

Study participating centre
County Emergency Clinica Hospital “Sf. Apostol Andrei”
Tomis Boulevard, 145
Constanta
Romania
900591

Study participating centre
Elias University Emergency Hospital
Mărăști Boulevard, 17
Bucharest
Romania
011461

Study participating centre

Mures County Clinical Hospital
Bernády György Square, 6
Targu Mures
Romania
540072

Study participating centre
Ambulatory Practice for Primary Outpatient Medical Care SANA OOD
8 Akademic Stefan Mladenov Street
Sofia
Bulgaria
1700

Study participating centre
BROD - Ambulatory Practice for Primary Medical Care EOOD
23 Petko D. Petkov Str
Plovdiv
Bulgaria
4000

Study participating centre
Medical Centre Prolet EOOD
25 Olimpi Panov Str., fl. 2
Ruse
Bulgaria
7000

Sponsor information

Organisation
Novintethical Pharma (Switzerland)

ROR
https://ror.org/05ypvb778

Funder(s)

Funder type
Industry

Funder Name
Novintethical Pharma

Results and Publications

Individual participant data (IPD) sharing plan
The data will be collected under 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 current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2023	11/08/2023	Yes	No