ISRCTN11118799 https://doi.org/10.1186/ISRCTN11118799

Evaluation of Dermasectan cream versus standard of care to compare their effectiveness and safety in treating atopic dermatitis (eczema) in children

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
24/11/2021

Overall study status
Completed

Last Edited
25/09/2023

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 (eczema) is a condition that makes the skin red and itchy that can appear during early childhood and often before the age of 2 years. This study aims to evaluate the effectiveness and safety of Dermasectan cream in pediatric patients with atopic dermatitis. The study also aims to evaluate the effectiveness of Dermasectan cream, compared to the Standard of Care, in reducing the symptoms of this condition.

Who can participate?
Children aged between 6 months and 12 years old with atopic dermatitis on the standard of care treatment (e.g. hydrocortisone) or on Dermasectan

What does the study involve?
The study lasts for 28 days, with two applications per day for 14 consecutive days of treatment with one of the study products: Dermasectan cream or the standard of care (e.g. hydrocortisone). There are four study visits at day 0, day 8 (after 7 days of treatment), day 15 (after 14 days of treatment), and day 29 (14 days after the end of treatment, a phone-call visit).

What are the possible benefits and risks of participating?
This treatment could be very helpful for the treatment of atopic dermatitis by reducing the symptoms associated with this diagnosis. The treatment may bring personal benefits or this may not be the case. The results of this study could help discover new treatments for atopic dermatitis. 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?
March 2019 to May 2020

Who is funding the study?
Novintethical Pharma SA (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 (0)737 640 721
alina.iordache@cebis-int.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
DERCBS1806

Study information

Scientific Title
A prospective, multicenter, comparative study of Dermasectan versus standard of care (e.g. hydrocortisone) in the current clinical practice using subjective assessment in children with atopic dermatitis

Acronym
ADVANCE

Study objectives
To evaluate the clinical efficacy of Dermasectan in alleviating the symptomatology of atopic dermatitis, based on the patient’s subjective assessment.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 13/06/2019, The 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: 7SNI

Study design
Prospective multicenter comparative study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
Each patient was enrolled after the doctor decided to prescribe Dermasectan or SoC (e.g. hydrocortisone 10 mg / g ointment) and met the eligibility criteria in a 1:1 ratio. Dermasectan was provided by the Study Sponsor.

After signing the informed consent, each subject was evaluated for eligibility criteria. 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 SoC (e.g. hydrocortisone).

Each subject was physically examined (weight, height). The investigator evaluated the atopic dermatitis status evolution by using the following questionnaires during each visit: ADSI, SCORAD and POEM. Medical history and demographic data (including subject's initials, date of birth) and medication used was recorded into the patient file. All subjects attended four visits during the study:
Visit 1 – Day 0
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 the end of treatment) – phone-call visit

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
Efficacy assessed by:
1. Erythema, pruritus, exudation, excoriation, crusted erosions and lichenification assessed using

a 4-point (0-3) scale - the Atopic Dermatitis Severity Index (ADSI) - recorded at visits on day 0, day 8 and day 15
2. Redness, swelling, oozing/crusting, scratch marks, skin thickening (lichenification) and dryness measured using the SCORAD (Score Atopic Dermatitis) Calculator at the doctor’s office at the time of the visits on day 0, day 8 and day 15
3. Patient chart assessment by the Patient Oriented Eczema Measure (POEM) recorded at visits on day 0, day 8 and day 15

Key secondary outcome(s))
Safety outcomes (percentage of participants who experienced an adverse event, number of drop-outs due to side effects, disease progression) evaluated during the study visit on day 8, day 15 and day 28

Completion date
01/05/2020

Eligibility

Key inclusion criteria
1. Children aged between 6 months and 12 years old
2. Children with a confirmed diagnostic of atopic dermatitis
3. Patients initiated on standard of care for atopic dermatitis (e.g. hydrocortisone) or children initiated on Dermasectan at the moment of signing the informed consent
4. Informed consent signed according to local legislation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
12 years

Sex
All

Total final enrolment
42

Key exclusion criteria
1. Illness within the past 4 days before study enrollment or any medical condition that may affect the risk of study participation
2. Active diagnosis or history of other severe dermatological conditions

3. Concomitant use of medications that may affect the study; products that could have a similar effect as the investigated products (e.g. corticosteroids, anti-inflammatories)
4. Previous allergic reaction or known sensitivity to ingredients in study agents

Date of first enrolment
20/08/2019

Date of final enrolment
10/04/2020

Locations

Countries of recruitment
Romania

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

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

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

Study participating centre
Medical Office of Dermatology Prof. Dr. Orasan Remus Ioan
21 Decembrie 1989 Boulevard, 23-25
Cluj Napoca
Romania
400105

Study participating centre
Family Medicine Dispensary Dr. Cristian Gainaru
Dambovita
Romania
-

Sponsor information

Organisation
Novintethical Pharma (Switzerland)

ROR
https://ror.org/05ypvb778

Funder(s)

Funder type
Industry

Funder Name
Novintethical Pharma SA

Results and Publications

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

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/09/2023	25/09/2023	Yes	No