

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	<input type="checkbox"/> Prospectively registered
Registration date 24/11/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/09/2023	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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: ADASI, 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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2019

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

Age group

Child

Lower age limit

6 Months

Upper age limit

12 Years

Sex

Both

Target number of participants

42

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
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Study participating centre
Medical Office of Dermatology Prof. Dr. Orasan Remus Ioan
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400105

Study participating centre
Family Medicine Dispensary Dr. Cristian Gainaru
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Sponsor information

Organisation
Novintethical Pharma (Switzerland)

Sponsor details
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Sponsor type
Industry

Website
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ROR
<https://ror.org/05ypvb778>

Funder(s)

Funder type

Industry

Funder Name

Novintethical Pharma SA

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. Additional documents will be provided at a later point. Additional documents will be available on request.

Intention to publish date

15/05/2022

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