

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

<b>Submission date</b> 16/11/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 24/11/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/09/2023	<b>Condition category</b> 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  
alina.iordache@cebis-int.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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  
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  
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## **Sponsor information**

**Organisation**  
Novintethical Pharma (Switzerland)

**Sponsor details**  
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**Sponsor type**  
Industry

**Website**  
<http://www.novintethical.com/>

**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?
<a href="#">Results article</a>		23/09/2023	25/09/2023	Yes	No