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Study on the tolerance and efficiency of a dermo-cosmetic product for mild to moderate acne in combination or comparison to current treatments in Romania

Submission date
01/02/2023

Recruitment status
No longer recruiting

Registration date
11/12/2023

Overall study status
Completed

Last Edited
04/11/2024

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
The aim of this study is to evaluate Teen Derm A.Z, a triple action care against persistent blemishes and marks and ultra-soothing that is applied on the face area.

Who can participate?
Patients with acne-prone skin. For groups 2 and 3 patients should begin an anti-acne treatment (zinc orally, antibiotic orally, contraceptive or hormonal treatment, topical retinoid, or a combination of these treatments).

What does the study involve?
First, the tolerance (cutaneous acceptability) of the treatment will be evaluated by clinical examination under dermatological control. Then, the effectiveness of the product in reducing acne lesions and marks (red and brown) will be assessed by the use of dermatological scoring and by comparing before and after pictures. Patient quality of life will be assessed and cosmetic acceptability and future use will be evaluated using a questionnaire.

What are the possible benefits and risks of participating?
The possible benefits are the improvement of acne severity.

Where is the study run from?
The study is run from two private dermatologists' offices in Romania

When is the study starting and how long is it expected to run for?
September 2022 to September 2023

Who is funding the study?
ISISPHARMA (France)

Who is the main contact?
Amélie Clément, aclement@isispharma.com

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2022-01

Study information

Scientific Title
Comparative efficacy and tolerability of a novel dermo-cosmetic cream with 15% azelaic acid for mild to moderate acne: a promising alternative to antibiotics

Study objectives
The product offers a good tolerance thanks to additional active ingredients and good efficacy on inflammatory lesions thanks to 15% azelaic acid.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study does not require ethics committee approval because it is conducted in private offices in Romania

Study design
Open-label observational study

Primary study design
Observational

Secondary study design

Cohort study

Study setting(s)
Other therapist office

Study type(s)
Quality of life, Treatment, Safety, Efficacy

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

Health condition(s) or problem(s) studied
Mild to moderate acne-prone skin

Interventions
The evaluated product is a cosmetic.

Group 1: only the cosmetic product applied twice per day
Group 2: cosmetic product applied once per day + concomitant treatment (according to the prescribing habits/needs of each patient)
Group 3: usual treatment according to the prescribing habits/needs of each patient

Evaluation of the tolerance (cutaneous acceptability) by clinical examination under dermatological control after 42 and 84 days of treatment
Evaluation of the efficacy in reducing acne lesions and marks (red and brown) by use of dermatological scoring at baseline and after 42 and 84 days
Evaluation of the global amelioration with before/after pictures at days 0, 42, and 84
Evaluation of the improvement of patient quality of life with the Cardiff Acne Disability Index (CADI) at days 0 and 84
Evaluation of the cosmetic acceptability and future use of the product by analysis of the subject' s answers to a subjective evaluation questionnaire on day 84
After 112 days, evaluation of the effects of stopping the treatment or product use after 1 month

Intervention Type
Other

Primary outcome measure
Tolerance (cutaneous acceptability) by clinical examination under dermatological control at baseline, 42, 84, and 72 days

Secondary outcome measures
1. Efficacy in reducing acne lesions and marks (red and brown) measured using dermatological scoring on days 0, 42, 84, and 112
2. Quality of life measured using the Cardiff Acne Disability Index (CADI) at days 0, 84 and 112

Overall study start date
26/09/2022

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Sex: female and/or male
2. Subject having given his/her informed written consent or parental authorization
3. Subject willing to adhere to the protocol and study procedures

Specific criteria:
1. Healthy subject with acne-prone skin: grade 2 or 3 (Global Acne Evaluation [GEA] scale) and with at least 10 inflammatory lesions
2. Group 2 and 3: Beginning an anti-acne treatment (zinc orally, antibiotic orally, contraceptive or hormonal treatment, topical retinoid or a combination)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
90

Total final enrolment
90

Key exclusion criteria
1. Excluding treatment:
1.1. Epiduo® or combination of benzoyl peroxide (BPO) + Adapalene
1.2. Oral isotretinoin
1.3. Chronically used anti-inflammatory drugs
2. Subject manipulating his/her acneic lesions
3. Any change in hormonal treatment (including contraceptives) during the three previous months of the study
4. Cutaneous pathology on the study zone (eczema, etc)
5. Excessive exposure to sunlight or UV rays within the previous month
6. Subject enrolled in another clinical trial during the study period

Date of first enrolment
01/10/2022

Date of final enrolment
01/03/2023

Locations

Countries of recruitment

Romania

Study participating centre
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Industry

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Funder(s)

Funder type
Industry

Funder Name
ISISPHARMA

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
04/07/2024

Individual participant data (IPD) sharing plan
Individual participant data are irretrievably and definitively anonymized, without the possibility of identification of the participant concerned, by the Investigator according to the standards in force guaranteeing complete confidentiality, prior to any transmission, display, or transfer to anyone.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			04/07/2024	No	No
Results article		02/11/2024	04/11/2024	Yes	No