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The benefit of a formulation of azelaic acid 15% and a complex of active ingredients for the treatment of papulopustular rosacea

Submission date
14/11/2022

Recruitment status
No longer recruiting

Registration date
16/01/2023

Overall study status
Completed

Last Edited
25/07/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Azelaic acid (AZ) is a first-line choice for the treatment of papulopustular rosacea (PPR) but secondary rosacea symptoms, including itching, stinging, and burning as well as skin hypersensitivity and hyperirritability can limit treatment efficacy. This study evaluates the efficacy of a novel multifunctional facial cream (named β-AZ cream) containing AZ 15% and an active ingredient complex in alleviating primary and secondary symptoms of PPR.

Who can participate?
Male and female adults with a diagnosis of papulopustular rosacea phenotype and a minimum of 10 inflammatory lesions

What does the study involve?
Subjects were enrolled in a 12-week trial and assigned to one of the three groups: the tested cream (β-AZ group, n=24), metronidazole 0.75% cream (MZ group, n=23), or a vehicle cream (vehicle group, n=22). Clinical efficacy such as inflammatory lesions, erythema and Investigator Global Assessment (IGA) score were evaluated at baseline and each study visit (week 4, 8 and 12). Patients' subjective assessment of overall skin improvement was assessed after 12 weeks. Secondary symptoms were also determined at weeks 4, 8 and 12.

What are the possible benefits and risks of participating?
The study is carried out using cosmetic products whose safety has been assured by the Sponsor. Its aim is to further confirm, under normal and reasonably foreseeable use conditions, the capacity of products to maintain the human body in good condition and reduce the symptoms of rosacea. The tested product is a formulation of topical azelaic acid 15% associated with a complex of natural active ingredients with soothing, anti-redness, repairing, and moisturizing properties. Both azelaic acid and the control metronidazole 0.75% are indicated for the treatment of rosacea and are well tolerated. Most reported adverse events include transient redness, and itching.

Where is the study run from?
Department of Dermatology, Hospital Universitario de La Samaritana (Colombia)

When is the study starting and how long is it expected to run for?
December 2017 to April 2020

Who is funding the study?
ISISPHARMA (France)

Who is the main contact?
Amélie Clément (Isispharma - Dewavrin Group), aclement@isispharma.com (France)

Contact information

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Additional identifiers

Protocol serial number
2018-01

Study information

Scientific Title
Evaluating the Efficacy of a Novel Dermocosmetic Cream with 15% Azelaic Acid and Active Ingredients Complex, Presenting Soothing and Non-Irritant Properties, in Treating Papulopustular Rosacea: Results from a Randomized Trial

Study objectives
Current study hypothesis as of 25/07/2024:

A multifunctional facial cream composed of azelaic 15% and a complex of active ingredients with soothing, anti-redness, repairing and moisturizing properties could alleviate primary and secondary symptoms of Papulopustular rosacea

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Previous study hypothesis:

A multifunctional facial cream composed of azelaic 15% and a complex of active ingredients with soothing, anti-redness, repairing and moisturizing properties is more efficacious than metronidazole 0.75% for relieving specific symptoms associated with Papulopustular rosacea phenotype

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval by an institutional review board was not required in Colombia for studies performed on cosmetic products or pre-existing molecules

Study design
12-week single-centre double-blind vehicle-controlled parallel-assigned-group randomized clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Papulopustular rosacea phenotype

Interventions

This study is a 12-week, double-blind, vehicle-controlled, parallel-assigned-group, randomized clinical trial performed in one centre in Colombia enrolling subjects with papulopustular rosacea randomly assigned to one of three intervention groups: the tested AZ cream (AZ group, n=24), metronidazole 0.75% cream (MZ group, n=23), or a vehicle cream (placebo group, n=22). The randomization was performed using Excel by the sponsor, via an excel formula of random distribution in 3 columns in a homogeneous way. The blank tubes were then delivered to the investigators already coded. Disclosure of the assignment was performed at the end of the study. Each subject had an envelope with his or her treatment amount for the 3 months. All the subjects were instructed to apply the products twice daily in the morning and evening on the face from baseline for a period of 12 weeks and as recommended by the manufacturer. Follow-up visits were performed at baseline, and weeks 4, 8, and 12.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Metroruboril AZ, metronidazole 0.75%

Primary outcome(s)
Current primary outcome measure as of 25/07/2024:

Outcomes assessed at each study visit at baseline, and weeks 4, 8 and 12:
1. Number of inflammatory papules and pustules on the forehead, nose, both left and right cheek and chin counted by the investigator and recorded in the study records
2. Investigator global assessment (IGA) score measured using a 7-point static scoring system: (0: clear; 1: minimal; 2: mild; 3: mild to moderate; 4: moderate; 5: moderate to severe; 6: severe).
3. Global improvement in erythema severity measured using the Clinical Erythema Severity Score (ESS) on a 3-point scale ranging from 0: mild to 2:severe
5. Secondary symptoms assessment for the following clinical signs: burning, itching, and dryness measured using a 4point scale (0: none to 3: severe)

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Previous primary outcome measure:

Outcomes assessed at each study visit at baseline, and weeks 4, 8 and 12:
1. Number of inflammatory papules and pustules on the forehead, nose, both left and right cheek and chin counted by the investigator and recorded in the study records
2. Investigator global assessment (IGA) score measured using a 7-point static scoring system: (0: clear; 1: minimal; 2: mild; 3: mild to moderate; 4: moderate; 5: moderate to severe; 6: severe).
3. Global improvement in erythema severity measured using the Clinical Erythema Severity Score (ESS) on a 3-point scale ranging from 0: mild to 2:severe
4. Incidence of adverse events (AEs) reported by the investigator and recorded in the study records
5. Cutaneous tolerability for the following clinical signs: burning, itching, and dryness measured using a 4point scale (0: none to 3: severe)

Key secondary outcome(s))
Improvement in signs and symptoms of papulopustular rosacea phenotype measured using a self-assessment questionnaire with a 5-point scale (0: worse; 1: unchanged; 2: mild improvement; 3: moderate improvement; 4: great improvement) at week 12

Completion date
30/04/2020

Eligibility

Key inclusion criteria
1. Male or female subjects aged 18 years and older
2. Clinical diagnosis of papulopustular rosacea (PPR) phenotype with at least 10 inflammatory lesions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
69

Key exclusion criteria
1. Pregnant or nursing woman
2. Subjects with rosacea of predominant phenotypes different from the phenotype of papules and pustules
3. Subjects with concomitant dermatoses that might interfere with the evaluation of lesions
4. Concomitant use of oral antibiotics and/or oral isotretinoin
5. Contraindications for the use of azelaic acid or metronidazole

Date of first enrolment
01/10/2018

Date of final enrolment
30/11/2019

Locations

Countries of recruitment

Colombia

Study participating centre
Hospital Universitario de La Samaritana, Department of dermatology
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Sponsor information

Organisation
ISISPHARMA

Funder(s)

Funder type
Industry

Funder Name
ISISPHARMA

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Carolina Ivette Cortés Correa (Kritocor@yahoo.com)

IPD sharing plan summary
Available on request