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Efficacy and safety of a fixed combination of benzoyl peroxide 4% and niacinamide 4% in a polyvinyl alcohol and perfluoro-ether polymer-based cream for the treatment of mild to moderate inflammatory rosacea

Submission date 02/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/12/2025	**Overall study status** Completed	
Last Edited 02/12/2025	**Condition category** Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Principal investigator, Scientific

Contact name
Dr Massimo Milani

Contact details
Via Milano, 160
Caronno Pertusella
Italy
21042
+39 (0)280030205
massimo.milani@difacooper.com

Additional identifiers

Study information

Scientific Title

Efficacy and safety of a fixed combination of benzoyl peroxide 4% and niacinamide 4% in a polyvinyl alcohol and perfluoro-ether polymer-based cream for the treatment of mild to moderate inflammatory rosacea: a prospective assessor-blinded pilot trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/01/2025, Comitato Etico Locale Catania 1 (Via Santa Sofia,78, catania, 95123, Italy; +39 (0)954794036; celct1@policlinico.unict.it), ref: DIICA-2025

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Blinded (masking used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Mild to moderate inflammatory rosacea

Interventions
The patients were instructed to apply 0.25 ml of the tested product to the affected facial areas once daily at bedtime for 8 weeks. A mild, fragrance-free, hypoallergenic facial fluid cleanser, along with broad-spectrum sunscreen (SPF 50+) for the daily skincare routine were recommended.

Intervention Type
Other

Primary outcome(s)

1. Overall treatment efficacy measured using IGA score at baseline, T1 (4 weeks), and T2 (8 weeks)
2. Erythema measured using a 4-point scale (from 0 = none, to 3 = severe erythema) at baseline, T1 (4 weeks), and T2 (8 weeks)

Key secondary outcome(s))
1. The evolution in the number of papule and pustular lesions measured by counting the number of inflammatory lesions at baseline, T1, and T2
2. Instrumental evaluation of erythema performed using VISIA-CR imaging at baseline, T1, and T2
3. Local tolerability of the product evaluated using a tolerability score (from score 0= very well tolerated, no pain/burning feeling and dryness feeling; to score 4= very intense pain/burning /dryness feeling) at T1 and T2

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Diagnosis of mild to moderate inflammatory rosacea (≥ 5 papulopustular lesions), according to the Global ROSacea Consensus (ROSCO) panel (2019)
2. Wash-out period of at least 15 or 30 days for previous topical or systemic pharmacological agents for rosacea, respectively

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
26 years

Upper age limit
67 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Concomitant other inflammatory facial dermatoses
2. Known hypersensitivity or allergies to any components of the tested formulation
3. Pregnancy or breastfeeding

Date of first enrolment
27/01/2025

Date of final enrolment
01/07/2025

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Cantabria Labs Difacooper

Funder(s)

Funder type

Funder Name
Cantabria Labs Difacooper

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date