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Testing the safety and effectiveness of a new cream in men with seborrheic dermatitis of the face and chest

Submission date
16/10/2019

Recruitment status
No longer recruiting

Registration date
17/10/2019

Overall study status
Completed

Last Edited
11/11/2019

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
Seborrheic dermatitis (SD) is a common condition that causes redness of the skin, flaking/scaling and dandruff. It is thought that excess oil production in the skin and overgrowth of Malassezia furfur (a type of yeast fungus that is normally found on the skin) can contribute to SD. Nutradeica is a cream that contains agents that reduce fungal growth, oil production and inflammation. This study aims to investigate whether Nutradeica can treat SD.

Who can participate?
Men aged 21-65 years who have SD on their face and chest, but otherwise are in good health.

What does the study involve?
All participants will apply the cream to their face and chest twice daily for 14 days. Before the start of treatment, at 7 days after the start of treatment and at 14 days after the start of treatment, they will have skin scrapings and small skin samples taken, fill in some forms to assess their SD symptoms and be assessed by the researchers.

What are the possible benefits and risks of participating?
The possible benefit to participants is that the cream may improve their SD symptoms and their microbial skin flora may be re-balanced. The possible risks related to the skin sample procedure are represented, in the worst cases, by a spot about 2 mm of slightly different complexion (lighter or darker) than the surrounding skin or a small scar of 2 mm, similar to a chicken pox scar

Where is the study run from?
Dermatology Unit of University of Naples Federico II (Italy)

When is the study starting and how long is it expected to run for?
May 2017 to April 2019

Who is funding the study?
ISDIN, the company that makes Nutradeica

Who is the main contact?
Javier Bustos, javier.bustos@isdin.com

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2019-003813-32

Protocol serial number
ISD-CL-DE-1058-01-2017

Study information

Scientific Title
Experimental, prospective, open, monocenter, clinical trial for the evaluation of a novel cream used to improve the condition of seborrheic dermatitis topically applied on face and chest in patients with seborrheic dermatitis

Study objectives
The pathogenesis of seborrheic dermatitis (SD) is multifactorial and traditional treatments may not target all aspects of them.The aim of this study was to evaluate short term anti-fungal, anti-microbial, anti-inflammatory and anti-pruritus properties of a novel non-steroidal cream (NSC) containing piroctone olamine, zinc PCA, hydroxyphenyl propamidobenzoic acid, biosaccharide gum-2 and stearyl glycyrrhetinate in patients with face and chest SD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/03/2018, Ethics Committee for Biomedical Activities “Carlo Romano” of University of Naples Federico II (Dipartimento di Scienze Biomediche Avanzate, Via S. Pansini, 5-80131 Napoli, Italy; +39 (081)7463468 e-mail: comitato.etico@unina.it), ref: 35/18

Primary study design
Interventional

Study design
Single-centre prospective open-label trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Seborrheic dermatitis

Interventions
Patients were instructed to apply Nutradeica cream twice daily on the face and on the chest for 14 days. The investigator evaluated their skin condition at first visit and after 7 and 14 days of product use. A physican will perform skin scale scraping from the face (wings of the nose) and the chest through the study. In addition, the physician will perfom a biopsy (2 mm diameter) in the same area on the chest at first visit and after 7 days product use.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nutradeica (containing active agents piroctone olamine , zinc PCA, hydroxyphenyl propamidobenzoic acid, biosaccharide gum-2 and stearyl glycyrrhetinate)

Primary outcome(s)
1. Severity of seborrheic dermatitis assessed using a scoring index (SI) evaluating erythema, desquamation, itching and irritation at baseline and after 7 and 14 days of treatment
2. Seborrheic dermatitis severity assessed using the Investigator's Global Assessment Score (IGA) at baseline and after 7 and 14 days of treatment

Key secondary outcome(s)
1. Patient evaluation of erythema assessed using a visual analog scale at baseline and after 7 and 14 days of treatment
2. Patient evaluation of scaling assessed using a visual analog scale at baseline and after 7 and 14 days of treatment
3. Patient evaluation of itching assessed using a visual analog scale at baseline and after 7 and 14 days of treatment
4. Patient evaluation of sensation of heat assessed using a visual analog scale at baseline and after 7 and 14 days of treatment
5. Patient evaluation of pain assessed using a visual analog scale at at baseline and after 7 and 14 days of treatment
6. Patient evaluation of irritation assessed using a visual analog scale at baseline and after 7 and 14 days of treatment
7. Patient evaluation of seborrheic dermatitis severity change assessed using the Patient Global Assessment (PGA) after 7 and 14 days of treatment

8. Antifungal effect assessed by quantifying Malassezia furfur colony-forming units from skin scrapings at baseline and after 7 and 14 days of treatment
9. Antimicrobial effect assessed by quantifying Staphylococcus epidermidis colony-forming units from skin scrapings and gene expression of antimicrobial peptides (HBD2 and HBD3) at baseline and after 7 and 14 days of treatment
10. Anti-inflammatory effect assessed by quantifying gene expression of IL-1α, IL-1β, IL-6, IL-8 and TNF-α in skin biopsies at baseline and after 7 and 14 days of treatment
11. Anti-pruritic effect assessed by quantifying gene expression of cathepsin S (CTS) and L-histidine decarboxylase (HDC) in skin biopsies at baseline and after 7 and 14 days of treatment
12. Tolerability assessed by quantifying adverse events recorded by the investigator or reported by patients during the study

Completion date
01/04/2019

Eligibility

Key inclusion criteria
1. Males in otherwise good health
2. Aged 21-65 years at time of enrollment
3. Mild to moderate visible SD on face and chest area

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Total final enrolment
12

Key exclusion criteria
1. Acute or chronic disease or medical condition that could put participant at risk in the opinion of the Principal Investigator or compromise study outcomes
2. History of allergic reactions, skin sensitization and/or known allergies to cosmetic ingredients, toiletries, sunscreens, etc.
3. Immunocompromised
4. Taking other medications (oral or topical) that could interfere with the interpretation of the results

Date of first enrolment
11/04/2018

Date of final enrolment

22/02/2019

Locations

Countries of recruitment
Italy

Study participating centre
Dermatology Unit of University of Naples Federico II
Universita Di Napoli Federico II
Azienda Ospedaliera Universitaria Federico II
Dip. Ad Attivita Integrata di Medicina Clinica
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Sponsor information

Organisation
ISDIN S.A.

ROR
https://ror.org/04dg86p75

Funder(s)

Funder type
Industry

Funder Name
ISDIN S.A.

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.
Written informed consent from participants was obtained.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2020	11/11/2019	Yes	No