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Effect of a cream containing hyaluronic acid and bacterial wall extract on skin bacterial flora in subjects with facial seborrheic dermatitis

Submission date
30/10/2018

Recruitment status
No longer recruiting

Registration date
08/11/2018

Overall study status
Completed

Last Edited
30/12/2022

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 inflammatory skin disease, which commonly involves scalp, the face and sometimes the chest. These body areas are rich in sebaceous glands, which are involved in SD. SD is characterized by redness of the skin, oily skin, and itching. One cause of SD is the overgrowth of a particular type of fungus called Malassezia. Therefore, drugs or creams with anti-fungal activity could be beneficial in the treatment of SD. However, recent data has shown that SD leads to a change in the composition of the bacteria that live on the skin (bacterial skin flora). Some types of bacteria are reduced, whereas the population of other types is greatly increased. This trial aims to look at the effects of a new cream on reducing SD, and its effects on the composition of the bacterial skin flora.

Who can participate?
Adults with seborrheic dermatitis of the face

What does the study involve?
Participants will be provided with the study cream and asked to use it twice daily on their face for 6 weeks. They will have skin swabs taken at the start of the study, during the treatment and at the end of the treatment to evaluate their bacterial skin flora.

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 bacterial skin flora may be re-balanced. There are no known risks to participants taking part in this study.

Where is the study run from?
Three dermatology clinics in Italy:
1. Tor Vergata University (Rome)
2. Ospedale Le Torrette (Ancona)
3. Poliambulatorio Medica Plus (Modena)

When is the study starting and how long is it expected to run for?
February 2017 to May 2018

Who is funding the study?
Cantabria Labs Difa Cooper (Italy)

Who is the main contact?
Dr Massimo Milani MD
massimo.milani@difacooper.com

Contact information

Type(s)
Scientific

Contact name
Dr Massimo Milani

ORCID ID
http://orcid.org/0000-0001-7559-1202

Contact details
Via Milano 160
Caronno Pertusella
Italy
21042
+39029659031
massimo.milani@difacooper.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EutrosisDs02/2017

Study information

Scientific Title
Effects of a cream containing 5% hyaluronic acid conjugated with bacterial wall extract on signs and symptoms and on skin microbiota in subjects with seborrheic dermatitis of the face

Study objectives
A facial cream containing hyaluronic acid 5% complexed with a bacterial-wall-derived glycoprotein and peptide glycan complex (GPPG-complex) with a known immunomodulator action can equilibrate the facial microbiota in subjects with seborrheic dermatitis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of the Coordinating Center (Tor Vergata University, Rome), 22/02 /2017, 18bis/2017

Study design
Interventional prospective multi-center open assessor-blinded non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Seborrheic dermatitis of the face

Interventions
Participants will be provided with a cosmetic cream containing hyaluronic acid 5%, bacterial wall ferment, zinc PCA, climbazole, piroctone and glycyrrhetinic acid, to be used twice daily on the face (2 finger tip units (FTU) for each application), once in the morning and once in the evening, for 6 weeks.
There will be no follow-up period.

Intervention Type
Other

Primary outcome measure
The Investigator Global Assessment (IGA) is used at the baseline, week 3 and week 6 to assess the following:
1. Erythema
2. Seborrhea
3. Itching

Secondary outcome measures
Evolution of superficial facial microbiota in the following areas:
1. Interglabellar
2. Naso-labial fold

3. Mandibular rim
This was assessed using 16Sr RNA gene sequencing at the baseline and after 6 weeks. Samples for RNA sequencing were obtained

The samples for RNA sequencing were obtained with Dry swabbing . Sample were taken in 3 different areas for each subject: Zone 2 Glabellar ; zone 2: nasolabial fold; Zone 3: mandibular rim. Swabs were stored a -80 C until the tests

Dry swab samples of the following areas were taken to assess superficial facial microbiota using 16S rRNA gene sequencing at the baseline and after 6 weeks:
1. Interglabellar
2. Nasolabial fold
3

Overall study start date
01/02/2017

Completion date
01/05/2018

Eligibility

Key inclusion criteria
1. Aged 20 years or older
2. Clinical diagnosis of moderate or severe seborrheic dermatitis
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70

Total final enrolment
75

Key exclusion criteria
1. HIV positive
2. Specific oral or topical treatments for seborrheic dermatitis (SD) in the previous 4 weeks
3. Pregnancy or breastfeeding
4. Known allergies to one or more component of the tested cream
5. Other inflammatory skin conditions other than SD
6. Use of oral probiotics in the previous 6 weeks
7. Cigarette smoking

Date of first enrolment
01/04/2017

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
Italy

Study participating centre
Dermatology Clinic University Tor Vergata
POLICLINICO TOR VERGATA Viale Oxford, 81 - 00133 Roma
Rome
Italy
00133

Study participating centre
Dermatology Clinic University of Ancona
Le Torrette Hospital
Via Conca
71
Ancona
Italy
60030

Study participating centre
Poliambulatorio Medica Plus
Viale dei Caduti in Guerra 101
Modena
Italy
41122

Sponsor information

Organisation
Difa Cooper

Sponsor details

Via Milano 160
Caronno Pertusella
Italy
21042
+39029659031
massimo.milani@difacooper.com

Sponsor type
Industry

ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Industry

Funder Name
Difa Cooper

Results and Publications

Publication and dissemination plan
We intend to publish the study results on an international peer-reviewed indexed scientific journal

Intention to publish date
01/01/2019

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 Massimo Milani (massimo.milani@difacooper.com). Raw data are stored in an Excel datasheet and will be stored for 10 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/11/2018	23/11/2018	No	No
Results article		02/05/2019	30/12/2022	Yes	No