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

Submission date	Recruitment status No longer recruiting	Prospectively registered			
30/10/2018		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
08/11/2018	Completed	[X] Results			
Last Edited 30/12/2022	Condition category Skin and Connective Tissue Diseases	[] 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

https://orcid.org/0000-0001-7559-1202

Contact details

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

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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Completion date

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

ROR

https://ror.org/044sr7e96

Funder(s)

Funder type

Industry

Funder Name

Difa Cooper

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 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?
Results article		02/05/2019	30/12/2022	Yes	No
Basic results		02/11/2018	23/11/2018	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes