

Anti-itch effectiveness of a new cream containing emollient and moisturizing components

Submission date 07/10/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/10/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/03/2022	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chronic nodular prurigo (CNPG) is a skin disease characterized by itchy papules and nodules that is usually resistant to standard treatment and associated with markedly reduced quality of life. Chronic itching is the most relevant clinical feature of this condition. The aim of this study is to evaluate the effectiveness of a cosmetic cream containing emollient lipids and three different anti-itching components in patients with CNPG.

Who can participate?

Patients aged 60 or over with CNPG

What does the study involve?

The trial will involve 2 weeks of treatment with a total of three visits (at the start and after 1 and after 2 weeks). There is no follow up. Each participant will be instructed to apply 1.5 g of the cream to the forearm (both sides) twice daily (morning and evening). Itch intensity is evaluated before and after 2 weeks' treatment using questionnaires.

What are the possible benefits and risks of participating?

The potential benefit of the study is finding an effective topical treatment able to reduce the intensity of itch in this clinical condition. The risk is considered very low, no invasive diagnostic procedures are used.

Where is the study run from?

Tor Vergata and San Gallicano Hospitals (Italy)

When is the study starting and how long is it expected to run for?

June 2020 to November 2020

Who is funding the study?

Difa Cooper (Italy)

Who is the main contact?
Massimo Milani MD
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Contact information

Type(s)

Public

Contact name

Dr Massimo Milani

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

POLCALM2/2020

Study information

Scientific Title

Efficacy of an omental lipid cream with specific anti-itching substances in prurigo nodularis patients

Study objectives

Prurigo nodularis is a common skin condition characterized by intense chronic itching and scratching representing a therapeutic challenge. A new emollient and moisturizing cream contains omental lipids and three components acting on different mechanisms involved in itch pathogenesis (Stimu-Tex, Polidocanol and palmitoylethanolamide). The study hypothesis is to evaluate the anti-itching efficacy of this new cream evaluated by a specific tool (VAS, Pruritus questionnaire).

Ethics approval required

Old ethics approval format

Ethics approval(s)

The evaluated product is a marketed cosmetic not requiring specific ethics approval. Nevertheless, the trial is conducted according to GCP and the Helsinki Declaration. All subjects will provide written informed consent prior to participation.

Study design

Interventional prospective investigator-blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prurigo nodularis

Interventions

The tested product is a cream containing purified omental lipid, polidocanol, PEA (palmitoylethanolamide). The trial will involve 2 weeks of treatment with a total of three visits (at baseline and after 1 and after 2 weeks). There is no follow up. Each participating subject will be instructed to apply the tested cream on the forearm (both sides) twice daily (morning and evening) using a dose of 3 Finger Tip Units for application (1.5 g of cream each application).

Intervention Type

Other

Primary outcome(s)

Evolution of itch sensation at baseline and week 2 using:

1. Pruritus Visual Analogue Scale (0-100 mm) (P-VAS), a mono-dimensional scale for assessment of itch intensity
2. Numerical Rating Scale (NRS) from 1 to 10

Key secondary outcome(s)

1. Grade of acanthosis measured using Optical Coherence Tomography (Vivascope UK) device at baseline and week 2
2. Hyperkeratosis measured using Optical Coherence Tomography (Vivascope UK) device at baseline and week 2
3. Vascular signal measured using Optical Coherence Tomography (Vivascope UK) device at baseline and week 2

Completion date

30/11/2020

Eligibility

Key inclusion criteria

1. Age over 60 years
2. Men and women
3. Clinical diagnosis of prurigo nodularis affecting at least both arms

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Acute or chronic skin conditions characterized by itching (with the exclusion of prurigo nodularis)
2. Medical internal conditions characterized by chronic itching (renal insufficiency, chronic liver disease, haematological conditions like lymphoma, polycythemia etc)

Date of first enrolment

15/10/2020

Date of final enrolment

02/11/2020

Locations**Countries of recruitment**

Italy

Study participating centre

Dermatology Clinic University Tor Vergata

Viale Oxford 80

Rome

Italy

00100

Study participating centre

Dermatology Clinic Istituto San Gallicano

Via Elio Chianesi, 53, 00144

Rome

Italy

0144

Sponsor information

Organisation

Difa Cooper (Italy)

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 MD (massimo.milani@difacooper.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/12/2020	15/03/2022	Yes	No