ISRCTN86956166 https://doi.org/10.1186/ISRCTN86956166

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

Submission date	Recruitment status	[X] Prospectively registered
07/10/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/10/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/03/2022	Skin and Connective Tissue Diseases	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

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 informtion sheet

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 measure
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

Secondary outcome measures
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

Overall study start date

01/06/2020

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

Age group
Senior

Sex
Both

Target number of participants
20

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
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Study participating centre
Dermatology Clinic Istituto San Gallicano
Via Elio Chianesi, 53, 00144
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Sponsor information

Organisation
Difa Cooper (Italy)

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Sponsor type
Industry

Website
http://www.difacooper.com/

ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Industry

Funder Name
Difa Cooper

Results and Publications

Publication and dissemination plan
The results of this trial will be collected and analysed in order to produce a manuscript to be sent to a peer-reviewed scientific journal. All the study documentation is stored at the participating center and could be available on request.

Intention to publish date
01/05/2021

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