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Efficacy of a novel cream with antiedema function in the treatment of cellulite

Submission date
10/07/2017

Recruitment status
No longer recruiting

Registration date
13/07/2017

Overall study status
Completed

Last Edited
11/07/2018

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
Gynoid lipodystrophy, also known as cellulite, is a very common skin alteration (such as dimples or bumpy) that is mainly a cosmetic concern rather than a real disease. For many people it is very concerning as they do not like the way it looks. Cellulite can be treated through lasers, liposuction (surgical procedure that removes fat) as well as topic treatments (such as creams). However, an effective treatment of cellulite has not been well established. The aim of this study is to evaluate the effect of an anti-cellulite cream on the appearance of cellulite on the thigh.

Who can participate?
Women aged 18 to 65 who have cellulite.

What does the study involve?
Participants are asked to apply a cream once daily for 60 days in the body area affect by cellulite (gluteal regions, thighs and buttock). Participants attend study visits one and two months after using the cream to measure their thigh circumference and have pictures taken of certain areas to assess their cellulite levels.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
This study is being run by Difa Cooper (Italy) and takes place in Medica Plus Modena Via Bernini Coordinator Centre (Italy) and private dermatology services in Naples (Italy)

When is the study starting and how long is it expected to run for?
September 2016 to June 2017

Who is funding the study?
Difa Cooper (Italy)

Who is the main contact?
Dr Massimo Milani

Contact information

Type(s)
Scientific

Contact name
Dr Massimo Milani

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Contact details
Difa Cooper
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of a novel hypertonic draining cream for cellulite reduction: a Clinical and instrumental (Antera 3D) assessment

Study objectives
The aim of this study is to evaluate the effect of an anticellulite cream on thigh circumference and skin profilometry assessed by Antera 3D.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medica Plus Service Modena, 20/10/2016

Study design
Interventional randomised controlled trial

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Gynoid lipodystrophy (Cellulite)

Interventions
Participants are given an hypertonic topical product with draining action (HTC cream) that contains NaCl 13%, escine, caffeine and beta-sytosterol. They are asked to apply it once daily on their thighs, gluteal and buttock regions for 60 days.

Participants are assessed at baseline, one and two months to measure their thighs (this procedure is done by an evaluator (office clinic nurses) blinded to the type of treatment. Measurements are done with the participant standing and measuruing up to 25 cm from the superior pole of the patella.
Participant also undergo computer analysis of their skin to asses their cellulite levels at baseline and two months. The Antera 3D CS images system measures in an objective and operator-independent manner the volume of skin protrusions and depressions of a pre-specified area. Volume of depressions in the target zone are expressed in mm3.

Intervention Type
Other

Primary outcome measure
1. Thigh circumferential is measured using a flexible measuring ruler with the participant in standing position and performing the measurement up to 25 cm from the superior pole of the patella at baseline, one and two months
2. Computer-analysis of skin profilometry of a pre-specified target area (in general in the zone above the trochanteric eminence or gluteal zone) evaluated by means of Antera 3D CS (Miravex, Dublin, Ireland) at baseline and two months

Secondary outcome measures
Cellulite (skin appearance) are measured using the orange peel severity score (0 to 5) before and after the pinch test at baseline, one and two months.

Overall study start date
30/09/2016

Completion date

20/06/2017

Eligibility

Key inclusion criteria
1. Women aged 18-65 years
2. Have grade II-IV gynoid lipodystrophy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Previous treatment (within 2 months of the study period) for cellulite (topical or oral)
2. Positive history for lower limbs venous or lymphatic insufficiency
3. Pregnancy or breast feeding
4. Positive history of allergic contact dermatitis to any of the component of the cream

Date of first enrolment
01/11/2016

Date of final enrolment
30/03/2017

Locations

Countries of recruitment
Italy

United Kingdom

Study participating centre
Medica Plus Modena Via Bernini Coordinator Centre
Modena

Italy
-

Study participating centre
Private Dermatology Service Naples
Naples
Italy
-

Sponsor information

Organisation
Difa Cooper

Sponsor details
Via Milano 160
Caronno Perusella
Italy
21042

Sponsor type
Industry

Website
www.difacooper.com

ROR
https://ror.org/044sr7e96

Funder(s)

Funder type
Industry

Funder Name
Difa Cooper SpA

Results and Publications

Publication and dissemination plan

Planned publication in a Pubmed Indexed international high-impact peer reviewed Journal by the end of October 2017.

Intention to publish date
31/10/2017

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. Data have been stored as Excel file.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018		Yes	No