

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

Submission date 10/07/2017	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 13/07/2017	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 11/07/2018	Condition category Skin and Connective Tissue Diseases	☐ 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 affected 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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Difa Cooper
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Additional identifiers

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

Primary study design

Interventional

Study design

Interventional randomised controlled trial

Study type(s)

Quality of life

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 measuring 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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

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

United Kingdom

Italy

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

ROR

<https://ror.org/044sr7e96>

Funder(s)

Funder type

Industry

Funder Name

Difa Cooper SpA

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. 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