

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

<b>Submission date</b> 10/07/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/07/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/07/2018	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

## ORCID ID

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

## Contact details

Difa Cooper

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# Additional identifiers

## Protocol serial number

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

## 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 mm<sup>3</sup>.

### 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

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**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?
<a href="#">Results article</a>	results	01/06/2018		Yes	No