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The effect of a food supplement based on a mixture of herbal extracts on cellulite and weight control

Submission date
13/07/2018

Recruitment status
No longer recruiting

Registration date
24/07/2018

Overall study status
Completed

Last Edited
06/11/2019

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cellulite is a skin condition that can lead to skin imperfections, caused by uneven distribution of fat, It is seen most commonly in the thighs, hips and abdomen of both women and men. Exercise and a healthy diet can reduce the appearance of cellulite, but cannot completely eliminate it. Weight loss is key to reducing cellulite, whether this is achieved by diet or through exercising to burn calories and increase metabolism.
Herbal supplements can help to achieve weight loss faster than diet or exercise alone, as they increase the rate of burning fats. Some supplements containing compounds from plants can also help to reduce cellulite through removing toxins, draining fluids, reducing inflammation and firming and toning the skin, along with burning fat.
The aim of this study is to determine the efficacy of SelectSIEVE® Rainbow, a food supplement that contains a mixture of herbal and plant extracts including black rice, kiwi, orange and pineapple extract, on reducing the appearance of cellulite and on weight control.

Who can participate?
Healthy women aged 18-55 with cellulite and a BMI ranging from 23-30

What does the study involve?
Participants will be asked to take one capsule per day, containing either the food supplement (SelectSIEVE® Rainbow) or a placebo, for 56 days. Participants will be evaluated for changes in the appearance of their cellulite, skin elasticity and firmness, thickness of fatty layers and body measurements such as weight and circumferences. These measurements will be taken before starting the treatment, after 28 days and after 56 days. Participants will also be asked to take part in an interview for a self-assessment evaluation.

What are the possible benefits and risks of participating?
The possible benefit to participants is a reduction in the appearance of cellulite-related skin imperfections and a slimming effect. There are no known risks to participants, aside from a minimal risk of allergy or intolerance to the food supplement.

Where is the study run from?
Complife Italia S.r.l, Sam Martino Siccomario, Pavia, Italy

When is the study starting and how long is it expected to run for?
November 2017 to April 2018

Who is funding the study?
ROELMI HPC S.r.l (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
E.HU.039-0060.01.003L_2018/288

Study information

Scientific Title
Randomized, double blind, placebo controlled clinical study for evaluating the efficacy of a food supplement on cellulite-derived skin imperfections and weight control

Study objectives
The present study is aimed to assess the efficacy of food supplement based on a mixture of herbal extract (SelectSIEVE® Rainbow), in ameliorating cellulite-derived skin imperfections as well as on the weight control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Independent Ethical Committee for Non-Pharmacological Clinical Study Trials, 02/02/2018, ref 2018/01

Study design
Interventional double-blind placebo-controlled single-centre parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Cellulite-derived skin imperfections and localised adiposity at level of thighs/hip/waistline

Interventions
60 healthy female participants were randomly allocated evenly into either the treatment or placebo group using a computer generated restricted randomisation list. Participants in the treatment group took capsules containing the active product (SelectSIEVE® Rainbow), a food supplement containing a mixture of herbal extracts, maltodextrins and natural dye. Participants in the placebo group took placebo capsules, where the active product was substituted by maltodextrins. Both groups took 1 capsule per day with a drink of water, either before lunch or their main meal, for 56 days. Participants in both groups were asked to follow a personalised alimentary diet, calculated in order to reduce their daily calorie intake by 300 kcal. Participants were also asked to use a body cream in place of their standard cream for body care.

Intervention Type
Supplement

Primary outcome measure

The following outcomes were measured at day 0 (beginning of the treatment), day 28 and day 56 of treatment:
1. Cellulite-induced alteration of the skin microcirculation, measured by thermographic imaging
2. Clinical-dermatological evaluation of the cellulite-derived skin imperfections ("Orange peel" skin appearance) carried out by a dermatologist in accordance to clinical scores
3. Thickness of the subcutaneous fatty layer measured by an ultrasound technique (using BX2000 BodyMetrix)
4. Skin elasticity and firmness, measured on the thighs by a Cutometer®

Secondary outcome measures
The following outcomes were measured at day 0 (beginning of the treatment), day 28 and day 56 of treatment:
1. Body weight by electric balance and height by stadiometer (for BMI determination)
2. Body circumferences (tights, hips, waistline) by a flexible meter
3. Evaluation of safety (adverse effects and tolerability) by monitoring adverse effects

4. Self-assessment evaluation, assessed using a 12 question questionnaire carried out after 28 and 56 days of treatment

Overall study start date
10/11/2017

Completion date
03/04/2018

Eligibility

Key inclusion criteria
1. Good general health
2. Female
3. Caucasian ethnicity
4. Age between 18 and 55 years old
5. Mild to moderate cellulite-derived skin imperfections (grade II and III of the cellulite thermographic stage)
6. BMI between 23 and 30.
7. Not been recently involved in any other similar study
8. Willing to follow the proposed alimentary diet for all the study time
9. Willing to use only the cream consigned at the beginning of the study for body care
10. Willing to submit to before and after pictures
11. Willing to use only the food supplement during the entire study period
12. Willing to not use products likely to interfere with the food supplement
13. Willing to not vary the normal daily routine (i.e. lifestyle, physical activity, etc.)
14. Under effective contraception (oral/not oral) that is not expected to be changed during the trial
15. Aware of study procedures and signed informed consent form

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60

Key exclusion criteria
1. Pregnant or intending to become pregnant during study
2. Breastfeeding
3. Atopy (if this interferes with the study)
4. Allergic to ingredients of food supplements
5. Allergies to cosmetic products, toiletries, sunscreens and/or topical drugs
6. Following anti-cellulite treatment or have followed an anti-cellulite treatment less than 3 months before the study
7. Used sunbeds or self-tanning product for one month before study or intend to use it during the study
8. Using pharmacological treatment (local or systemic) that may interfere with study
9. Intending to initiate any intensive sport
10. Other diseases that may affect outcome of study, especially metabolic or endocrine (e.g. diabetes, liver disease, kidney disorders) or any other condition that the principal investigator deems inappropriate for participation
11. Protected by the law (under guardianship, hospitalised in a public or private institution or incarcerated)
12. Unable to communicate or cooperate with the investigator

Date of first enrolment
05/02/2018

Date of final enrolment
07/02/2018

Locations

Countries of recruitment
Italy

Study participating centre
Complife Italia Srl
Via Mons. Angelini 21
San Martino Siccomario (PV)
Italy
27028

Sponsor information

Organisation
ROELMI HPC Srl

Sponsor details
Via Celeste Milani 24
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Italy
21040

Sponsor type
Industry

Website
https://roelmihpc.com/

Funder(s)

Funder type
Not defined

Funder Name
ROELMI HPC Srl

Results and Publications

Publication and dissemination plan
Data will published in relevant international peer reviewed journals.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository on a proprietary server. Tables and pictures will be shared and will become available after editing and sending the final report to the sponsor. Datasets will be available for 10 years. The prinicipal investigator and control authorities (on request) can access data for analyses including anthropometric measures, calculations and pictures. Access will be granted via a personal password. Consent from participants was obtained and all data is anonymised through coding. There are no ethical or legal restrictions.

IPD sharing plan summary

Stored in repository