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Strength gel with Kaempferia Parviflora Extract for improving the appearance of cellulite.

Submission date
31/03/2025

Recruitment status
Stopped

Registration date
12/04/2025

Overall study status
Stopped

Last Edited
11/03/2026

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims
A proof-of-concept (POC) study with Strength Gel has demonstrated efficacy in the treatment of moderate to severe cellulite. No safety issues were identified in the proof of concept study that evaluated twice per day topical administration in healthy volunteers for 3 months. The current study seeks to confirm the POC results using an established cellulite grading scale (Merz cellulite dimple scale) applied by blinded evaluators.

Who can participate?
Women in generally good health aged 25 to 65 years who do not anticipate gaining or losing a large amount of weight in the coming months.

What does the study involve?
The study involves using a marketed cosmetic product (Strength Gel) twice per day and coming into the study centers once per month for a short session where photos will be taken.

What are the possible benefits and risks of participating?
The primary possible benefit of participating in the study is the potential to reduce the appearance of cellulite on the treated side of the body during the study (and on the untreated side of the body after the completion of the study as participants will get additional product to treat the untreated side after completing the study). There are no anticipated risks from participating in the study. The test product contains ingredients with a low risk of irritation. None of the ingredients in the test product are known to present any risk to an unborn baby.

Where is the study run from?
The study is run by Adipeau Inc., the United States of America, with study centers in the US, the UK and Australia.

When is the study starting and how long is it expected to run for?
March 2025 to July 2026. The study started recruiting in May 2025 and is expected to run for 12 months.

Who is funding the study?
Adipeau Inc.

Who is the main contact?
Ivan Galanin, ivan@adipeau.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mr Ivan Galanin

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Additional identifiers

Protocol serial number
SBG-002

Study information

Scientific Title
A multi-site, blinded study assessing the efficacy of a lipolytic and adipogenic agent (Kaempferia Parviflora Extract) as a treatment for cellulite

Acronym
KPE-FORCEL

Study objectives
The principal hypothesis being tested is that a topical cosmetic product comprising Kaempferia Parviflora Extract can improve the appearance of cellulite as evaluated by the Merz cellulite scale.

Ethics approval required
Ethics approval not required

Ethics approval(s)

The study evaluates a cosmetic product that is publicly available without a prescription for topical use and has a strong safety profile.

Study design
A pre-post controlled split-body study

Primary study design
Interventional

Study type(s)
Efficacy, Safety, Treatment

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

Interventions
This pre-post study compares the effect of the test product vs. no product on the appearance of cellulite severity at specific target areas. The treatment comprises the cosmetic product "Strength Gel" registered in the EU and UK. The subject will administer sufficient amounts of the test product to cover areas of cellulite on the treatment target areas on the right side of their bodies twice per day, in the morning and the evening. The amount to be applied depends on the size of the treated area, but ranges from a US nickel-sized dollop to a US quarter-sized dollop.

Up to 8 target areas of cellulite severity will be selected for evaluation by each study coordinator after the baseline visit photography. Up to 4 target areas are to be treated with the Test Product on the right side of the body, and up to 4 areas on the left side of the body will not be treated. Cellulite appearance will be documented by 2D imaging at 5 study sites and by 3D imaging at one of the 5 study sites. The subjects are not blinded. The 2D imaging results will be assessed by blinded evaluators who will not know which images are pre- or post-treatment. Subjects are required to visit the study center every 4 weeks for evaluation.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Kaempferia Parviflora Extract Strong Body Gel

Primary outcome(s)
Current primary outcome measure as of 14/10/2025:

The difference in the grade of cellulite severity on treated areas vs. untreated areas at 12 weeks as measured by the Merz cellulite dimple scale.

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Previous primary outcome measure:

The grade of cellulite severity measured using the Merz Aesthetics cellulite dimple grading scales by blinded evaluators at 12 weeks

Key secondary outcome(s))
Current secondary outcome measures as of 14/10/2025:

1. The difference in the grade of cellulite severity in the treated areas after 12 weeks vs. at baseline as measured by the Merz cellulite dimple scale.
2. The difference in cellulite severity in the treated areas after 12 weeks vs. at baseline as measured by Antera 3D imaging.
3. The difference in the ability of evaluators to identify “before” images based on a higher cellulite severity grade being assigned to those images according to the Merz cellulite dimple scale.

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Previous secondary outcome measures:

1. The grade of cellulite severity measured using the Merz Aesthetics cellulite dimple grading scales by blinded evaluators at baseline and after 12 weeks
2. Cellulite severity measured using Antera 3D imaging at baseline and after 12 weeks
3. The ability of evaluators to identify “before” images based on a higher cellulite severity grade being assigned to those images according to the Merz cellulite dimple scale at one time point

Completion date
21/07/2026

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/02/2026:
1. Subjects with mild to severe cellulite as measured by the Merz cellulite dimple scale
2. Female subjects aged 25-75 years
3. Subjects with Fitzpatrick skin types I-VI
4. Subjects who are dependable and able to follow directions, and willing to comply with the schedule of visits
5. Subjects in generally good physical and mental health

Previous inclusion criteria:
1. Subjects with mild to severe cellulite as measured by the Merz cellulite dimple scale
2. Female subjects aged 25-65 years
3. Subjects with Fitzpatrick skin types I-VI
4. Subjects who are dependable and able to follow directions, and willing to comply with the schedule of visits
5. Subjects in generally good physical and mental health

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
25 years

Upper age limit
75 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Subjects diagnosed or treated for lipedema or lymphedema
2. Subjects with known allergies to the ingredients in the Test Product
3. Subjects who are pregnant or nursing
4. Subjects who anticipate engaging in activities that would result in significant weight loss or gain in the three months following screening

Date of first enrolment
21/05/2025

Date of final enrolment
07/04/2026

Locations

Countries of recruitment
United Kingdom

England

Australia

United States of America

Study participating centre
Julia Hart Facialist
7 Constitution Hill
Gravesend
England
DA12 1JT

Study participating centre
Nectar Skin Studio
40 E Main St, Suite 240
Bozeman
United States of America
59715

Study participating centre
South County Microspa
31991 Dove Canyon Drive, Suite 100 A
Rancho Santa Margarita
United States of America
92688

Study participating centre
Non-Surgical Youth & Beauty Clinic
723 Virginia Dr.
Orlando
United States of America
32803

Study participating centre
Skin by Summer
50 Tallis Drive
Mornington
Australia
3931

Sponsor information

Organisation
Adipeau Inc

Funder(s)

Funder type
Industry

Funder Name
Adipeau Inc

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request from Ivan Galanin (ivan@adipeau.com). The dataset consists of de-identified baseline and 3-month follow-up photographs of the treated and untreated legs of participants with cellulite. All images will be coded in matched before/after pairs and will contain no direct personal identifiers.

Data will be available after publication of the primary study results and will remain accessible for five years thereafter.
Access to the data will be granted only to qualified academic researchers for scientific, non-commercial analyses related to dermatology, adipose tissue biology, cellulite, image-based assessment, or closely related clinical research fields. Requests will be assessed for scientific merit and ethical appropriateness.

To obtain access, researchers must:
1. Submit a formal data-access request including a brief proposal describing the intended analyses
2. Agree to use the data solely for the approved research purpose
3. Sign a data-use agreement prohibiting re-identification of participants, data sharing with third parties, or any commercial use

Participant consent for data sharing was obtained as part of the study's informed consent process. All photographs will be anonymised prior to release, and no information that could reasonably identify a participant will be shared. Data sharing will comply with all applicable ethical and legal requirements.

No additional restrictions apply beyond the access and use criteria stated above.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (other)		02/12/2025	04/12/2025	No	No