

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

Submission date 31/03/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/02/2026	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

ORCID ID

<https://orcid.org/0000-0002-8991-9552>

Contact details

Adipeau Inc, 8 East 96th Street
New York
United States of America
10128
+1 9176287920
ivan@adipeau.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

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.

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.

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

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