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

Submission date	Recruitment status	[X] Prospectively registered
31/03/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/04/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2025	Skin and Connective Tissue Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
A proof-of-concept (POC) study with the Strong Body 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 (Strong Body 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 UK and Australia.

When is the study starting and how long is it expected to run for?
March 2025 to December 2025. The study starts recruiting in May 2025 and is expected to run for 3 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Community, Other therapist office, Other

Study type(s)
Treatment, Safety, Efficacy

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

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 "Strong Body 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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

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

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

Overall study start date
21/03/2025

Completion date
21/12/2025

Eligibility

Key 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

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
40

Total final enrolment
48

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
21/07/2025

Locations

Countries of recruitment
Australia

England

United Kingdom

United States of America

Study participating centre
Julia Hart Facialist
7 Constitution Hill
Gravesend
United Kingdom
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

Sponsor details
8 East 96th Street
New York
United States of America
10128

Sponsor type
Industry

Website
https://adipeau.com/

Funder(s)

Funder type
Industry

Funder Name
Adipeau Inc

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/06/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date