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Can semaglutide, a GLP-1 agonist, which mimics a hormone that regulates appetite and blood sugar levels, help non-obese people achieve and maintain weight loss

Submission date
12/03/2025

Recruitment status
No longer recruiting

Registration date
17/03/2025

Overall study status
Completed

Last Edited
09/04/2025

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
This study assesses the efficacy of compounded semaglutide (GLP-1 agonist), the active ingredient of an FDA-approved weight loss drug for patients with obesity, for weight loss and weight maintenance in otherwise healthy normal and overweight people (BMI < 29.9). The study will also evaluate safety, efficacy, extent of weight loss with likely consequential health benefits and define a novel, and likely lower, dosing regimen for semaglutide (GLP-1 agonist) for weight loss in a non-obese population. The study plans to propose a novel method to declare the ideal or target weight which bridges the difference in body composition, bone structure and sex. Achieving a target weight is also proposed to measure the success of the weight loss program. The 'success zone' is defined as within 75% of the target weight.

Who can participate?
Healthy volunteer men and women aged 21-82 years old

What does the study involve?
Weekly doses, dose adjustments, when semaglutide (GLP-1 agonist) was stopped, when target weight was attained, and weight maintenance were collected. No diet was prescribed. This is an ongoing rolling database.

What are the possible benefits and risks of participating?
Benefits include weight loss. Risks may include common side effects such as nausea, gastrointestinal discomfort, and rare adverse reactions, which will be managed through continuous medical support.

Where is the study run from?
Sharon Giese, MD, private medical office.

When is the study starting and how long is it expected to run for?
April 2022 to May 2025

Who is funding the study?
Investigator initiated and participants self-funded care

Who is the main contact?
Dr. Sharon Giese, sgiesemd@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Sharon Giese

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Sharon Giese, MD
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Additional identifiers

Study information

Scientific Title
Use of semaglutide for successful elective weight loss in a non-obese population and likely health benefits

Study objectives
Semaglutide can be used for successful weight loss in the non-obese population.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/03/2025, BeyondBound Institutional Review Board (IRB) (1980 Festival Plaza Dr. Suite 300, Las Vegas, 89135, United States of America; +1 646-217-0403; info@beyondbound.org), ref: BB2503SG-083

Study design
Observational non-randomized single-center study design with two follow-ups

Primary study design

Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Weight loss and the benefits

Interventions
This internal, prospective, non-randomized, non-blinded, dynamic, cohort observational study was conducted at Dr Sharon Giese's aesthetic medicine practice located in New York City, from May 2022 until the present. All standard ethical guidelines were followed. A single intervention, administration of compounded, subcutaneous, semaglutide was objectively assessed for its effectiveness in aiding weight loss, primarily in the non-obese population (BMI <29.9). Participants will undergo a structured elective weight loss program that includes the administration of semaglutide at doses that do not exceed FDA-approved guidelines. The intervention will involve regular monitoring of weight, nutritional monitoring, and medical supervision to ensure adherence and safety. Participants will receive detailed education on the medication, its potential side effects, and strategies for managing any adverse reactions. Weekly follow-ups will be conducted via email and in-person or virtual consultations to assess progress and address any concerns.

Patients stayed on medication until their target weight was attained. Following the maintenance of the target weight, the medication dose was incrementally decreased, as long as weight loss was maintained. Patients had the choice to stay on the medication or discontinue it at any time.

Data will be collected through a combination of medical observations, patient self-reports, and structured follow-ups. Participants will track their weight, dietary habits, and any side effects using standardized forms and weekly check-ins. Medical records will be reviewed to document progress, adherence to the program, and any reported adverse events. Surveys and questionnaires will be administered periodically to assess participants' experiences, satisfaction, and overall well-being. All data will be securely stored in compliance with HIPAA regulations to ensure confidentiality and accuracy.

All participant data will be anonymized by assigning unique identification codes to ensure privacy. Confidential information will be securely stored in an encrypted, password-protected system, with access restricted to the principal investigator and authorized research staff. Any physical documents will be kept in a locked cabinet within a secure office to prevent unauthorized access. Data will be retained for the required period in compliance with ethical and legal guidelines and will then be permanently deleted or securely destroyed. These measures will ensure that participant confidentiality is maintained throughout the study.

The protocol for the compounded semaglutide medication with cyanocobalamin (B12) (5/ 0.5mg /1cc) was to inject 0.25mg or 5 units of medication subcutaneously into your thigh or abdomen, once weekly and check in with the office or nutritional coach to titrate the dose for appetite suppression, dosing and timing was adjusted as necessary to achieve appetite suppression and weight-loss. If patients experienced adverse events, such as reflux, nausea, vomiting, or diarrhea, medication was discontinued until symptoms resolved for three days. The maximum dose will never exceed 2.4 mg. Patients with sustained weight loss plateaus or a slow rate at higher doses of semaglutide and patients with insulin resistance were switched to tirzepatide/niacinamide (17/ 2 mg/1cc), with doses ranging from 2.5 to 15 mg. Data are also collected from the patients

regarding, achieving target weight, and weight maintenance, whether with or without medication. Patients will stay on the medication until the target weight is achieved or at what point they opt to stop losing weight. Data will continue to be collected through 2 years following the patients from day 0. The data is rolling and collection is ongoing with people being enrolled weekly. The stated goal is: 1) weight loss, 2) weight maintenance and 3) to wean off the medication.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Semaglutide

Primary outcome(s)
Weight loss is measured by the participant taking their weight using a digital scale each morning. Patients have a recording sheet to record their weekly weight and medication dose. A photo is taken of the digital scale weight at days 0, 45, 180, and one and 2 years.

Key secondary outcome(s))
Defining the success of the weight loss program: Weight maintenance within the success zone will be assessed using regular weight measurements at baseline, 6 months, 1 year, and 2 years

Completion date
10/03/2026

Eligibility

Key inclusion criteria
1. Patients who were unable to attain their desired weight loss by any other means
2. 21 years old and over
3. Participants must agree to follow the prescribed treatment protocol, including weekly communication with a nutritional coach, weighing themselves, and adherence to medication dosage guidelines.
4. Participants who are taking semaglutide off-label must have consented and acknowledged the potential risks and outcomes.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
21 years

Upper age limit
82 years

Sex
All

Total final enrolment
326

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Taking medications such as metformin
3. Type 1 or type 2 diabetes or any other single co-morbidity
4. Individuals with BMI< 18.5 or > 40
5. A history of eating disorders
6. Severe gastrointestinal disorders
7. Severe adverse reactions to GLP-1 agonists, or other medical conditions that would pose a risk in a weight loss program
8. Unable to comply with follow-up procedures

Date of first enrolment
20/04/2022

Date of final enrolment
15/05/2025

Locations

Countries of recruitment
United States of America

Study participating centre
Sharon Giese, MD
Townhouse 114, 114 East 61st street
New York
United States of America
10065

Sponsor information

Organisation
Sharon Giese, MD

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and participants self-funded care

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and analysed during the current study will be available upon request from Sharon Giese, MD, sgiesemd@gmail.com. Participants are anonymized to a number on a master Google doc. The sheet contains participants' sex, age, height, dose of semaglutide, and weight change over time. It also shows who has reached the target weight and success zone and who is off of the medication. All participants have given written consent. HIPPA and all ethical guidelines were followed. The master Google doc is available within one week on request in a view-only format.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			17/03/2025	No	No