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A phase II study to test the safety and effects of BC-006 Injection in adults with obesity

Submission date
02/04/2026

Recruitment status
No longer recruiting

Registration date
13/04/2026

Overall study status
Ongoing

Last Edited
10/04/2026

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Obesity can raise the risk of health problems such as type 2 diabetes, heart disease, heart failure, and fatty liver disease. BC-006 is a new type of medicine that works by entering liver cells and reducing the production of a protein called Activin E. This protein is involved in how the body stores fat. By lowering Activin E, BC-006 may help reduce body fat and improve lean muscle. The aim of this study is to see how safe BC-006 is, how the body processes it, how it affects the body, and which dose works best in adults with obesity.

Who can participate?
Adults aged 18 years to 70 years with a body mass index between 30 and 45 kilograms per square metre may be able to take part. Participants must have at least one obesity related condition, such as high blood pressure or high cholesterol, and their weight must have been stable in recent months. People cannot take part if they have certain medical conditions, diabetes, recent use of obesity treatments, or other findings that might make the study unsafe for them.

What does the study involve?
Participants will be placed into one of three groups at random. They will receive either BC-006 at different dose levels or a placebo. The study drug will be given as an injection under the skin on three occasions: Day 1, Day 30, and Day 115. Participants will then be followed for 170 days after their last dose. During the study, they will attend several visits for health checks, blood tests, heart monitoring, and scans that measure body fat and liver health.

What are the possible benefits and risks of participating?
The study may not provide direct benefit to those taking part. However, the information gained may help improve future treatments for obesity. Possible risks include side effects from the study drug, reactions at the injection site, and discomfort from study procedures such as blood tests. The study team will monitor participants closely to reduce these risks.

Where is the study run from?
The study is taking place at research centres in Australia located in Bayswater, Camberwell, and Sydney.

When is the study starting and how long is it expected to run for?
April 2026 to August 2027.

Who is funding the study?
BaseCure Therapeutics Inc. (Cayman Islands)

Who is the main contact?
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Contact information

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Public

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Study information

Scientific Title
A phase 2a, randomized, double-blind, placebo-controlled, monotherapy study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of subcutaneous injections of BC-006 in adults with obesity

Study objectives
The purposes of this study are:
1. To assess the safety and tolerability of BC-006 Injection in adults with obesity
2. To characterize the plasma PK of BC-006 Injection in adults with obesity
3. To assess the PD response of BC-006 Injection in adults with obesity
4. To characterize the plasma PK of BC-006 Injection metabolites in adults with obesity
5. To assess the preliminary efficacy of BC-006 Injection in adults with obesity
6. To assess the immunogenicity of BC-006 Injection in adults with obesity
7. To assess the PD effects of BC-006 Injection on biomarkers of obesity and lipolysis

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/04/2026, Bellberry HREC (123 Glen Osmond Road, Eastwood, 5063, Australia; +61 (08) 8361 3222; bellberry@bellberry.com.au), ref: 2026-02-331

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

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

Interventions
This is a Phase IIa, randomized, double-blind, placebo-controlled trial designed to evaluate the safety, tolerability, PK, PD, and efficacy of BC-006 administered via subcutaneous injection (SC) in adults with obesity. The study randomisation will be carried out by Medidata Randomisation and Trial Supply Management (RTSM) to randomise participants. During randomisation procedures, only the randomisation number will be displayed in the randomisation notice. The unblinded pharmacist will check against the randomisation list to ensure participants will receive IP or placebo.

This is a multi-dose group design where three treatment groups (Groups A to C), each comprising at least 12 subjects with obesity, will be enrolled to receive a SC dose of BC-006 Injection or placebo on Days 1 (dose 1), 30 (dose 2), and 115 (dose 3). Subjects will be followed for a total of 170 days after receiving their last dose.
The planned dosing strategy includes the following groups: Group A: 200 mg BC-006 Injection, Group B: 300 mg BC-006 Injection, Group C: Placebo

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
BC-006

Primary outcome(s)
1. Incidence and severity of Adverse Events (AEs) measured using AE assessments at End of Study

2. Incidence of CS laboratory abnormalities measured using hematology, serum chemistry, coagulation, and urinalysis test results at Screening, Days 1, 3, 8, 15, 30, 36, 57, 115, 200, 285 (EOS), ET

3. Incidence of CS abnormalities measured using 12-lead ECG parameters at Screening, Days 1, 285 (EOS), ET

4. Incidence of CS abnormalities measured using vital signs measurements at Screening, Days 1, 3, 8, 15, 30, 36,57, 115, 200, 285 (EOS), ET

5. Incidence of CS abnormalities measured using physical examination findings at Screening, Days 1, 3, 30, 115, 285 (EOS), ET

6. Incidence of CS abnormalities measured using C-SSRS findings at Screening, Days 1, 36, 285 (EOS), ET

Key secondary outcome(s)

1. PK parameters of BC-006 Injection measured using blood measurements of study drugs at Days 1, 30 and 115

2. Changes in absolute and % Total Body Fat, Android Fat, Gynoid Fat, Total Lean Mass, Visceral Adipose Volume, and Subcutaneous Adipose Volume from Baseline measured using DXA at D200 (end of blinded study period)

3. Changes in absolute and % body weight measured using body weight measurement from baseline at D200 (end of blinded study period)

4. Changes in absolute and % liver steatosis and fibrosis measured using Fibroscan at D200 (end of blinded study period)

Completion date
30/08/2027

Eligibility

Key inclusion criteria
1. Male and female subjects aged 18 to 70 years, inclusive, at the time of signing the informed consent
2. No clinically relevant abnormalities based on medical history, physical examinations, neurological examinations, clinical laboratory evaluations (hematology, serum chemistry, coagulation, urinalysis), and 12-lead ECG that, in the opinion of the Investigator, would affect subject safety
3. Body mass index (BMI) of ≥ 30 to < 45 kg/m2 at Screening
4. At least one additional obesity related complication (ORC) such as hypertension, hyperlipidemia, or stable cardiovascular disease. Medications to treat ORC must be unchanged for 30 days prior to Screening
5. Self-reported stable body weight (± 5%) for at least 3 months prior to Screening
6. Male participants must be willing to comply with protocol contraceptive requirements and agree to abstain from sperm donation for at least 6 months after last dose of IP
7. Female participants must not be pregnant or lactating and must be willing to comply with protocol contraceptive requirements until EOT
8. Agree to abstain from sperm or egg donation through 6 months after last dose of IP
9. Legally and ethically capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinically significant infection and/or cardiovascular, hematological, renal, hepatic, pulmonary, endocrine, gastrointestinal, immunological, dermatological, neurological, or psychiatric disease which could interfere with, or the treatment for which might interfere with, the conduct of the study or which would, in the opinion of the Investigator, unacceptably increase the subject's risk if he/she were to participate in the study
2. Diagnosed with type 1, type 2, or other autoimmune form of diabetes or clinical evidence of diabetes (for example hemoglobin A1c ≥ 6.5 percent, fasting blood glucose ≥ 126 mg/dL \[7.0 mmol/L] at screening, nonfasting glucose ≥ 200 mg/dL \[11.1 mmol/L] at screening, or use of any hypoglycemic drugs during screening or within 3 months prior to screening)
3. Subjects with any of the following
3.1. Transaminases (alanine aminotransferase, aspartate aminotransferase) greater than 3 × upper limit of normal (ULN)
3.2. Alkaline phosphatase (ALP) greater than 2 × ULN
3.3. Total serum bilirubin greater than 1.5 × ULN except subjects with Gilbert's syndrome at screening who are permitted if all other criteria are met
3.4. Platelet count less than 100,000/mm3
3.5. International normalized ratio (INR) greater than 1.3 in the absence of anticoagulants
3.6. Albumin less than 3.5 g/dL (subjects with abnormal but not clinically significant labs may be enrolled after input from the Medical Monitor)
4. History of moderate or more advanced renal disease at any time in the past or abnormal kidney function tests at screening (glomerular filtration rate less than 60 mL/min/1.73 m2 as estimated using the CKDEPI 2021 equation)
5. Clinically significant allergy to any type of drug at the discretion of the Investigator, or allergy to any constituents of BC006 Injection; history of anaphylaxis or hospitalization due to drug reaction
6. Any of the following abnormalities on triplicate 12lead ECG at screening
6.1. PR interval ≥ 210 msec
6.2. QRS complex ≥ 120 msec
6.3. Fridericia's corrected QT interval (QTcF) greater than 450 msec (males) and greater than 470 msec (females)
6.4. Any clinically significant abnormality on an ECG at the Investigator's discretion
7. Sitting or semisupine systolic blood pressure greater than 145 mmHg at screening, confirmed by repeat (up to 2 repeat attempts); systolic blood pressure between 145 and 165 mmHg may be allowed if considered stable and not clinically significant per Investigator judgement
8. Sitting or semisupine diastolic blood pressure greater than 95 mmHg at screening, confirmed by repeat (up to 2 repeat attempts); diastolic blood pressure between 90 and 105 mmHg may be allowed if considered stable and not clinically significant per Investigator judgement
9. Presence of birthmarks, tattoos, wounds, scars, blemishes, heavy hair, or other skin conditions at the planned dosing sites that could obscure observation of injection site reactions
10. Use of systemic antibiotics or immune suppressive medications within 30 days prior to investigational product dosing on Day 1; shortterm corticosteroid use (less than 30 days) is allowed
11. Use of any prescription or overthecounter medications or supplements for shortterm or chronic treatment of obesity within 3 months prior to screening

12. Any vaccination within 14 days prior to screening or anticipated live vaccination while participating in the study
13. Receipt of an investigational product or device, or participation in a drug research study, within 60 days (or 5 halflives of the drug, whichever is longer) or within 2 years from previous siRNA therapy before dosing on Day 1
14. Prior exposure to BC006 Injection at any time in the past
15. History of cytokine release syndrome
16. History of or active hyperinflammatory autoimmune diseases including but not limited to lichen planus, chronic urticaria, lupus, and vasculitis
17. History of postinflammatory hyperpigmentation (acquired melanosis)
18. History of or active severe atopic condition including but not limited to severe asthma and severe atopic dermatitis
19. Obesity primarily due to medication use, endocrinologic disorders, or genetic disorders such as PraderWilli syndrome
20. History of prior endoscopic, surgical, and/or devicebased treatments for obesity
21. History of hyperthyroidism or thyroidstimulating hormone levels less than 0.4 or greater than 6.0 mIU/L at screening; subjects with stable, wellcontrolled hypothyroidism who are clinically euthyroid on stable medication for at least 3 months prior to screening are eligible
22. History of malignancy within the last 2 years prior to screening except adequately treated basal cell carcinoma, squamous cell skin cancer, or in situ cervical cancer
23. History of major surgery within 90 days of screening or planned elective surgery during the study
24. Positive screen for hepatitis B surface antigen, hepatitis C antibody (if positive, amplification may be performed to confirm; cured hepatitis C can be enrolled), or HIV antibody
25. Positive alcohol breath test or positive urine drug abuse screen at screening or admission to clinical unit
26. Past or current history or evidence of drug or alcohol abuse, regular use of more than 3 units of alcohol per day (1 unit equals 150 mL wine, 360 mL beer, or 45 mL of 40 percent alcohol); use of illicit drugs within 6 months of screening (brief use of benzodiazepines or opiates with appropriate medical history may be permitted at Investigator discretion)
27. Donation of more than 500 mL of blood or plasma within 8 weeks prior to screening or planned donation through 90 days after the last dose of investigational product
28. Lifetime history of suicide attempt or affirmative answers to questions 4 or 5 on a ColumbiaSuicide Severity Rating Scale performed at screening

Date of first enrolment
24/04/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Australia

Study participating centre
Veritus Research
Building 21, 885 Mountain Highway

Bayswater
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3153

Study participating centre
Emeritus Research Camberwell
Ground Floor, 1096 Toorak Road
Camberwell
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3124

Study participating centre
Emeritus Research Sydney
Suite 2, Level 1, Building 2A, Lakes Business Park – North Precinct, 2-12 Lord Street
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Australia
2019

Sponsor information

Organisation
BaseCure Therapeutics Inc.

Funder(s)

Funder type

Funder Name
BaseCure Therapeutics Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available