ISRCTN83576037 https://doi.org/10.1186/ISRCTN83576037

A phase 2, safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy study of a subcutaneous injection of BC-006 and tirzepatide in adults with obesity

Submission date
16/01/2026

Recruitment status
Not yet recruiting

Registration date
27/01/2026

Overall study status
Ongoing

Last Edited
26/01/2026

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
BC-006 is a type of investigational medication called a small interfering ribonucleic acid (siRNA), which works in the liver to reduce the production of a protein called inhibin subunit beta E (INHBE). The purpose of the study is to investigate the effects of BC-006 combined with Tirzepatide in adult participants with obesity. Specifically, the study will evaluate how safe and well-tolerated the combination of BC-006 and Tirzepatide is in adult participants with obesity; measure levels of BC-006 and Tirzepatide in the blood over time, following each dose; measure the body's response to BC-006 and Tirzepatide; and assess the effect of BC-006 and Tirzepatide on body composition.

Who can participate?
Adults aged 18 – 65 years, with a BMI (Body Mass Index) between 30 - 50 kg/m2, stable body weight for at least 3 months prior to screening and at least one obesity-related complication such as high blood pressure, high cholesterol or triglycerides, fatty liver disease, or stable heart disease.

What does the study involve?
Participants may be on the study for (up to) 52 weeks, including a screening, dosing, and follow-up period. The study requires a 1-night stay at the research unit and 11 scheduled follow-up clinic visits. Study assessments include informed consent, eligibility check, history and demographics, vital signs, height, weight and waist-to-hip ratio, physical examination, injection site reaction monitoring, electrocardiogram (ECG), pregnancy tests / post-menopausal test, blood samples, urine samples, alcohol breath testing, and drug of abuse testing, health and medication check, mental health questionnaires, body composition scan, and liver ultrasound.

What are the possible benefits and risks of participating?
The study may not provide subjects with any therapeutic benefits. The information from this study might help to develop better treatments in the future for Obesity.

BC-006 has been well tolerated in a previous study in obese adults, with injection site reactions being the only risk directly associated with BC-006 dosing. The following adverse events were reported in the first study, considered to be mild and reversible:
- Diarrhea or constipation (2 participants)
- Decreased appetite/ Feeling full after eating a small amount of food (3 participants)
- Feeling tired (1 participant)
- Hypersensitivity reaction (1 participant)
- Dizziness when standing up and reduced mental clarity (1 participant)
- Mild rash (1 participant)
- Increased skin sensitivity (1 participant)
- Stomach cramps (3 participants)
- Feeling faint (1 participant)
- Redness/swelling/pain/itching around the injection site (17 participants)
Animal studies have also been done with BC-006 to try and predict what type of side effects might occur in people. However, animal studies do not always predict human responses to medications. When BC-006 was given to animals at doses higher than the doses that will be given in this study, no adverse (harmful) side effects were seen. The below effects were observed in animal studies:
- Changes in liver cells and functions
- Skin reactions at the injection site

Where is the study run from?
New Zealand Clinical Research- Christchurch

When is the study starting and how long is it expected to run for?
The study is starting in February 2026 and is expected to run until August 2027

Who is funding the study?
This research project is being conducted and funded by BaseCure Therapeutics Inc.

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
A Phase II, randomized, double-blind, placebo-controlled, combination therapy trial to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of subcutaneous injections of BC-006 and tirzepatide in adults with obesity

Acronym
BCT-BC-006-201

Study objectives
The purposes of the study are to:
1. Evaluate how safe and well-tolerated BC-006 is in people with obesity.
2. Measure the levels of BC-006 in the blood over time, following two subcutaneous injections (SC) doses in combination with tirzepatide (TZP).
3. Measure the body's response following two doses of BC-006 in combination with tirzepatide

(TZP).
4. Measure the active byproducts of BC-006, how long they stay active and how they are cleared, especially when combined with tirzepatide (TZP).
5. Evaluate the effectiveness of BC-006 following two doses when used in combination with tirzepatide (TZP)

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 21/11/2025, Northern B Health and Disability Ethics Committee (Ministry of Health) (133 Molesworth Street, PO Box 5013, Wellington, 6011, New Zealand; +64 (0)800 855 066; hdecs@health.govt.nz), ref: 2025 FULL 24411

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Safety, Efficacy

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 combination therapy of BC-006 and tirzepatide (TZP), both administered via subcutaneous injection (SC), in adults with obesity. RTSM (randomization and trial supply management) is the name of the computer program used for randomisation. A pharmacist will be able to randomize manually if required, based on the randomization schedule provided to them (as a back-up). Two doses of BC-006 will be administered by subcutaneous injection (SC) in combination with weekly subcutaneous injection (SC) doses of tirzepatide (TZP). The participants will receive subcutaneous injection (SC) doses of 600 mg BC-006 or placebo on Days 1 and 85 along with a background of weekly subcutaneous injection (SC) doses of 2.5 mg or 5.0 mg tirzepatide (TZP).

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 from the time of BC-006 when dosed in combination with tirzepatide (TZP) to the End of Study

2. Incidence of laboratory abnormalities measured using hematology, serum chemistry, coagulation, and urinalysis test results, 12-lead ECG parameters and vital signs measurements at days -28, -1 (screening), 1, 3, 8, 22, 36, 57, 85 and 169, 253 post -dose and and day 337 (End of Study [EOS], early termination (ET)

3. Physical examination measured using a primary investigator physical exam at days -28, -1 (screening), 1, 3, 85 and 337 (End of Study (EOS, day 337 post-dose)/early termination (ET)

4. Suicide risk measured using Columbia-Suicide Severity Rating Scale (C-SSRS) at days -28, -1 (screening), 1, 36 and 169, 253 post dose and 337 (End of Study (EOS, day 337 post-dose)/early termination (ET)

Key secondary outcome(s))
1. Pharmacokinetics (PK) of SC doses of BC-006 when dosed in combination with tirzepatide (TZP) measured using blood measurements of study drug at days 1, 2, 3, 8, 85, 86, 87 post dose /early termination (ET)

2. Pharmacodynamic (PD) response following subcutaneous injection (SC) doses of BC-006 when dosed in combination with TZP in adults with obesity, measured using circulating biomarkers at days 1, 22, 36, 57, 85, 169, 253 post-dose and day 337 EOS, early termination (ET)

3. Pharmacokinetics (PK) of BC-006 metabolites following subcutaneous injection (SC) doses of BC-006 when dosed in combination with TZP in adults with obesity, measured using blood measurements of study drug at days 1, 2, 3, 8, 85,86 & 87 /early termination (ET)

Completion date
29/08/2027

Eligibility

Key inclusion criteria
1. Male and female subjects aged 18 to 65 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 electrocardiogram (ECG) that, in the opinion of the investigator, would affect participant safety.
3. Body mass index (BMI) of ≥30 to <50 kg/m2
4. Fibrosis-4 (Fib-4) score ≥1.4
5. At least one additional obesity related complication (ORC) such as hypertension,

hyperlipidemia, metabolic dysfunction-associated steatotic liver disease or stable cardiovascular disease, with the exception of Type 2 diabetes mellitus. Medications to treat ORC must be unchanged for 30 days prior to screening.
6. Self-reported stable body weight (±5%) for at least 3 months prior to screening.
7. Female participants must not be pregnant or lactating and must be willing to comply with protocol contraceptive requirements until EOT
8. Male participants must be willing to comply with protocol contraceptive requirements and agree to abstain from sperm or egg donation until EOT (Day 337).
9. Legally and ethically capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the ICF and in this protocol.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Clinically significant infection, 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 trial, or which would, in the opinion of the investigator, unacceptably increase the participant's risk to participate in the trial.
2. Diagnosed with diabetes (Type 1, 2 or other forms of diabetes mellitus, excluding a history of gestational diabetes and prediabetic participants with glycated hemoglobin [HbA1c] ≥6.5%).
3. Participants with any of the following: a. Transaminases (alanine aminotransferase [ALT], aspartate aminotransferase [AST]) >5 × upper limit of normal (ULN) b. Alkaline Phosphatase (ALP) >2 × ULN. c. Total serum bilirubin >1.5 × ULN except participants with Gilbert's syndrome at screening who are permitted if all other criteria are met d. Platelet count <100,000/mm3. e. International normalized ratio (INR) >1.3 in the absence of anticoagulants. f. Albumin <3.5 g/dL.
4. History of moderate or more advanced renal disease at any time in the past or abnormal kidney function tests at screening.
5. History of acute or chronic pancreatitis from any etiology, including but not limited to gallstone pancreatitis, at any time in the past.
6. Clinically significant allergy to any type of drug (anesthetics, antibiotics) at the discretion of the investigator, or allergy to any constituents of BC-006 or Tirzepatide (TZP). If there is any history of anaphylaxis/hospitalization due to drug reaction in the past, site should discuss further with the medical monitor, if needed.
7. Abnormalities on triplicate 12-lead ECG at screening.

8. Sitting or semi-supine (for at least 5 minutes) systolic blood pressure >160 mmHg at screening, confirmed by repeat.
9. Sitting or semi-supine (for at least 5 minutes) diastolic blood pressure >100 mmHg at screening, confirmed by repeat.
10. Presence of birthmarks, tattoos, wounds, scars, blemishes, heavy hair, or other skin conditions (such as eczema) at the planned dosing site/s that could be expected to obscure the observation of injection site reactions.
11. Use of antibiotics or immunosuppressive medications such as systemic steroids within 30 days prior to BC-006 dosing on Day 1.
12. Use of any medications including GLP-1 medications, OTC medications or herbal therapies for the short-term or chronic treatment of obesity within 3 months of screening.
13. Use of any anti-diabetic medications within 30 days of screening, or 90 days for GLP-1 medications.
14. Smoking >5 cigarettes per day (or nicotine equivalent) within 30 days prior to screening or anticipated use during the trial, and unable to abstain completely from smoking/vaping during the inpatient stay.
15. Any vaccination within 14 days prior to screening or anticipated live vaccination while participating in the trial.
16. Receipt of an investigational product or device, or participation in a drug research trial, within a period of 60 days (or 5 half-lives of the drug, whichever is longer) or within 2 years from previous siRNA therapy before dosing on Day 1.
17. Prior exposure to BC-006 at any time in the past.
18. Positive screen for hepatitis B surface antigen (HbsAg), hepatitis C antibody (if positive, amplification may be performed to confirm; cured hepatitis C can be enrolled), or human immunodeficiency virus (HIV) antibody.
19. Positive alcohol breath test or positive urine drugs of abuse screen at screening or Day 1.
20. Past or current history or evidence of drug or alcohol abuse.
21. Donation of more than 500 ml of blood or plasma within 8 weeks prior to screening or planned blood or plasma donation through 90 days after last dose of trial drug.
22. Any positive responses in the Columbia-Suicide Severity Rating Scale (C-SSRS) at screening that indicate the participant may be at increased risk by participating in this trial or may cause potential interference with trial conduct or results, at investigator discretion.
23. Clinically significant history of orthostatic hypotension at any time in the past.
24. Known serious hypersensitivity to TZP or other GLP-1-based therapy.
25. History of significant or prolonged intolerance to GLP-1-based therapy.
26. Personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia type 2.

Date of first enrolment
10/02/2026

Date of final enrolment
30/05/2026

Locations

Countries of recruitment
New Zealand

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