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A first-in-human study to test the safety and tolerability of an experimental medicine (CVTX-55832), given at different dose levels, in healthy volunteers

Submission date 26/08/2026	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol
Registration date 10/09/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 10/09/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to test a new investigational drug, CVTX-55832, compared with a placebo at different doses, to find out if it is safe and to understand the way people process the drug. A placebo looks like a drug but has no active ingredient.

Who can participate?
Healthy men and women aged 18 to 65.

What does the study involve?
The study has two parts. In Part 1, participants receive one dose of CVTX-55832 or a placebo, with the dose level increasing between successive groups of participants. In Part 2, participants receive multiple doses of CVTX-55832 or placebo.

Participants stay at the study site for a period of continuous monitoring after dosing, then attend follow-up visits so the study team can track safety and how the body responds.

What are the possible benefits and risks?
Participants are not expected to receive any direct benefits from the study, but the information that is learned may help develop a future treatment for people with autoimmune disease. CVTX-55832 has not yet been tested in humans. This is the first trial of CVTX-55832 in humans. For this reason, the effects of this drug are not known at this time.

Where is the study run from?
New Zealand Clinical Research.

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

Who is funding the study?
Covant Therapeutics Operating, Inc.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A first-in-human, phase I, randomised, double-blind, placebo-controlled, single-centre study evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of single and multiple ascending doses of CVTX-55832 in healthy participants

Study objectives
Primary:
To evaluate the safety and tolerability of single and multiple ascending doses of CVTX-55832 in healthy adult participants.

Secondary:
To determine the pharmacokinetic profile of CVTX-55832 following single and multiple ascending doses.
To determine the pharmacodynamic effects (change in IgG from baseline) of single and multiple ascending doses of CVTX-55832.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 31/08/2026, Northern Health and Disability Ethics Committees (HDEC), Ministry of Health (133 Molesworth Street, PO Box 5013, Wellington, 6011, New Zealand; -; hdecs@health.govt.nz), ref: 2026 FULL 26754

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
Healthy volunteers

Interventions
Method of randomization: Participants are allocated to CVTX-55832 or matching placebo (6:2 within each cohort) using a computer-generated permuted block randomisation schedule with a predefined allocation ratio, generated and finalised before first dose. Sealed participant-specific code-break envelopes are retained at site for emergency unblinding.

Part 1 (SAD): Eligible healthy adult participants will be enrolled and randomized to receive a single administration of CVTX-55832 or placebo at a ratio of 6:2. Part 1 provisionally plans for 5 sequential escalating single-dose cohorts. Escalation to the next cohort proceeds only after review of available safety, tolerability, and pharmacokinetic data. Dose levels are determined stepwise and are not fixed in advance. Participants who are randomised will be followed for up to 120 days.

Part 2 (MAD): Eligible participants for Part 2 will be enrolled and randomized at a ratio of 6:2 to receive multiple doses of CVTX-55832. Successive cohorts proceed only after review of available safety, tolerability, and pharmacokinetic data. Participants who are randomised will be followed for up to 176 days.

Specific dose levels, dosage form and route of administration are currently being treated as confidential development information and are therefore not disclosed.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
CVTX-55832

Primary outcome(s)
1. Adverse events (AEs), serious adverse events (SAEs), AEs leading to study treatment discontinuation from Day 1 through end of study measured using data collected from study records at the end of the study

Key secondary outcome(s)
1. Serum concentration of CVTX-55832 measured using a liquid chromatography–tandem mass spectrometry assay in blood samples at Days 1, 2, 3, 4, 5, 8, 11, 15, 19, 22, 29, 36, 43, 50, 57, 64, 71, 78, 85, 92, 99, 106, 113 and at End of Study (Day 120) in Part 1, and at Days 1, 2, 3, 8, 15, 22, 29, 30, 31, 36, 43, 50, 57, 64, 71, 78, 85, 92, 99, 106, 113, 120, 127, 134, 141, 148, 155, 162, 169 and at End of Study (Day 176) in Part 2

2. Serum concentration of pharmacodynamic parameters, including total IgG, measured using an immunoturbidimetric assay in blood samples at Screening, Day −1, and Days 1, 2, 3, 4, 5, 8, 11, 15, 19, 22, 29, 36, 43, 50, 57, 64, 71, 78, 85, 92, 99, 106, 113 and at End of Study (Day 120) in Part 1, and at Screening, Day −1, and Days 8, 15, 22, 29, 36, 43, 50, 57, 64, 71, 78, 85, 92, 99, 106, 113, 120, 127, 134, 141, 148, 155, 162, 169 and at End of Study (Day 176) in Part 2

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Healthy males and females who are aged 18 - 65 years
2. Body mass index between 18 - 32 kg/m2, with a body weight ≥50 kg and ≤100 kg at screening
3. Medically healthy, as determined by pre-study medical history, and without clinically significant abnormalities
4. Female volunteers:
4.1. Must agree not to donate ova from signing the ICF until the end of the study, AND
4.2. Must be of non-childbearing potential, OR
4.3. If of child-bearing potential, must:
4.3.1. Have a negative blood pregnancy test at the screening visit and a negative urine pregnancy test on admission to the study site on Day-1
4.3.2. Agree not to attempt to become pregnant or donate ova from signing the ICF until the end of the study
4.3.3. Agree to use a highly effective method of contraception from signing the ICF until the end of the study if not exclusively in a same-sex relationship or abstinent as a committed lifestyle
5. Male volunteers:
5.1. Must agree not to donate sperm from signing the ICF until the end of the study
5.2. If engaging in sexual intercourse with a female partner who could become pregnant, must agree to use adequate contraception from Day 1 until the end of the study
5.3. If engaging in sexual intercourse with a female partner who is not of childbearing potential or who is already pregnant, or a same-sex partner, must agree to use a condom from Day 1 until the end of the study

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. Known hypersensitivity to the study drug or any of the study drug ingredients
2. History of anaphylaxis or other significant allergy
3. History or presence of CS cardiovascular, pulmonary, hepatic, renal, haematological, gastrointestinal, endocrine, immunologic, dermatologic, psychiatric, or neurological disease /disorder, including any acute illness, within the past 3 months
4. History of surgery or hospitalisation within 3 months prior to screening, or surgery planned

during the study
5. Have an active malignancy or history of malignancy in the last 3 years
6. Presence of clinically relevant immunosuppression
7. A history of or positive test results for human immunodeficiency virus (HIV) or any history of hepatitis
8. History of or evidence of active or latent or inadequately treated infection with Mycobacterium tuberculosis diagnosed by a positive interferon gamma release assay
9. Administration of any systemic immunosuppressant agent within 6 months prior to initial study drug administration or longer if clinically relevant, i.e., B-cell depleting therapies

Date of first enrolment
07/10/2026

Date of final enrolment
16/03/2027

Locations

Countries of recruitment
New Zealand

Study participating centre
New Zealand Clinical Research (NZCR)
Main Building: 3 Ferncroft Street, Grafton
Screening HQ: 125 Grafton Road, Grafton
Satellite Site: 1B/300 Grey Street, Hamilton
Auckland
New Zealand

Sponsor information

Organisation
Covant Therapeutics Operating, Inc

Funder(s)

Funder type

Funder Name
Covant Therapeutics Operating, Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available