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Safety, tolerability, pharmacokinetics, and pharmacodynamics of single/multiple doses of IMVT-1402 in healthy participants and participants with autoimmune diseases

Submission date 09/05/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/05/2023	**Overall study status** Ongoing	
Last Edited 11/04/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The current approach is to observe the safety and tolerability of the study drug, how the drug moves within the body or pharmacokinetics (PK), and how it interacts with the body or pharmacodynamics (PD) in healthy volunteers and participants with autoimmune diseases.

Who can participate?
Healthy volunteers and participants aged between 18 to 55 years old and participants with autoimmune diseases aged between 18 and 75 years old.

What does the study involve?
This study consists of three parts. Part 1 will investigate the safety, tolerability, PK, and PD of single and multiple ascending doses (SAD and MAD) of IMVT-1402 in healthy adult male participants and adult female participants of non-childbearing potential (NCBP). In addition to the SAD and MAD cohorts, there is 1 Alternative Dose Regimen cohort that will receive study treatment or placebo. Up to approximately 108 participants will be enrolled in Part 1 of the study. In Part 1, eligible participants will be randomized to receive either study treatment or a placebo. Part 2 aims to investigate the safety, tolerability, PD, PK, and efficacy of 12 weeks of weekly SC dosing with IMVT-1402 in 48 adult participants with autoimmune diseases. In Part 2, all participants will receive study treatment. Part 3 of the study is an optional open-label long-term extension (LTE) and will include participants who have completed Part 2 and shown adequate clinical response in the opinion of the Investigator. The total duration of the LTE phase is 92 weeks, during which participants will continue receiving the same study treatment as in Part 2.
A total of up to approximately 156 participants will be enrolled in the study.

What are the possible benefits and risks of participating?
There is no direct benefit to participants in Part 1 of this study. However, the results of Part 1 of the study may lead to a better understanding and treatment of IgG autoantibody-mediated

diseases.
Participants in Part 2 and Part 3 may receive clinical benefits from participation in this study.

Where is the study run from?
Immunovant Sciences GmbH (Switzerland)

When is the study starting and how long is it expected to run for?
December 2022 to July 2028

Who is funding the study?
Immunovant Sciences GmbH (Switzerland)

Who is the main contact?
Dr Rohit Katial, rohit.katial@nzcr.co.nz

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IMVT-1402-1001

Study information

Scientific Title
A Phase I, randomized, double-blind, placebo-controlled, ascending dose study to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of IMVT-1402 following single and multiple doses in healthy participants and open-label cohorts in participants with autoimmune diseases

Study objectives
Current study hypothesis as of 11/04/2025:
Part 1 of the study aims to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single ascending doses (SAD), multiple ascending doses (MAD), and an alternative dose regimen of IMVT-1402 in healthy adult male participants and adult female participants of non-childbearing potential (NCBP). Part 2 aims to investigate the safety, tolerability, PD, PK, and efficacy of 12 weeks of weekly SC dosing of IMVT-1402 in adult participants with autoimmune diseases. Part 3 aims to evaluate the long-term safety and tolerability of IMVT-1402 in participants with autoimmune diseases.

Previous study hypothesis from 11/03/2024 to 11/04/2025:
Part 1 of the study aims to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single ascending doses (SAD), multiple ascending doses (MAD), and an alternative dose regimen of IMVT-1402 in healthy adult male participants and adult female participants of non-childbearing potential (NCBP). Part 2 aims to investigate the safety, tolerability, PD, PK, and efficacy of 12 weeks of weekly SC dosing of IMVT-1402 in adults with autoimmune diseases.

Previous study hypothesis as of 04/12/2023 to 11/03/2024:
Study to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single ascending doses (SAD), multiple ascending doses (MAD), and an alternative dose regimen of IMVT-1402 in healthy adult male participants and adult female participants of non-childbearing potential (NCBP).

Original study hypothesis:
Study to investigate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of single ascending doses (SAD) and multiple ascending doses (MAD) of IMVT-1402 in healthy adult male participants and adult female participants of non-childbearing potential (NCBP).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/05/2023, Central Health and Disability Ethics Committees (Ministry of Health, Health and Disability Ethics Committee, Wellington 6011, PO Box 5013, New Zealand; +64 0800 438 442; hdecs@health.govt.nz), ref: 2023 FULL 15579

Study design
Part 1 is an interventional randomized controlled double-blind study. Part 2 is an open-label study followed by Part 3, which is an optional open-label long-term extension

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthy volunteers and adults with autoimmune diseases

Interventions

Current interventions as of 11/04/2025:
In Part 1, participants will be randomized using simple randomization without stratification to receive either a single Intravenous (IV) Dose A, single IV Dose B, single subcutaneous (SC) Dose C, multiple SC Dose D, single IV Dose E, single SC Dose F, multiple SC Dose G, single IV Dose H, multiple SC Dose I (optional) and multiple SC Dose J (optional) of IMVT-1402 or placebo. The additional alternative dose regimen cohort will be randomized to receive either multiple SC Dose K of IMVT-1402 or placebo. IMVT-1402 and placebo are sterile SC or IV injections.
In Part 2 and Part 3, participants will receive open-label SC Dose G once weekly (QW). IMVT-1402 is a sterile SC injection.

Previous interventions from 11/03/2024 to 11/04/2025:
In Part 1, participants will be randomized using simple randomization without stratification to receive either a single Intravenous (IV) Dose A, single IV Dose B, single subcutaneous (SC) Dose C, multiple SC Dose D, single IV Dose E, single SC Dose F, multiple SC Dose G, single IV Dose H, multiple SC Dose I (optional) and multiple SC Dose J (optional) of IMVT-1402 or placebo. The additional alternative dose regimen cohort will be randomized to receive either multiple SC Dose K of IMVT-1402 or placebo. IMVT-1402 and placebo are sterile SC or IV injections.
In Part 2, participants will receive open-label SC Dose G once weekly (QW). IMVT-1402 is a sterile SC injection.

Previous interventions from 04/12/2023 to 11/03/2024:
Participants will be randomized using simple randomization without stratification to receive either a single Intravenous (IV) Dose A, single IV Dose B, single subcutaneous (SC) Dose C, multiple SC Dose D, single IV Dose E, single SC Dose F, multiple SC Dose G, single IV Dose H, multiple SC Dose I (optional) and multiple SC Dose J (optional) of IMVT-1402 or placebo. The additional alternative dose regimen cohort will be randomized to receive either multiple SC Dose K of IMVT-1402 or placebo. IMVT-1402 and placebo are sterile SC or IV injections.

Previous interventions from 23/05/2023 to 04/12/2023:
Participants will be randomized using simple randomization without stratification to receive either a single Intravenous (IV) Dose A, single IV Dose B, single subcutaneous (SC) Dose C, multiple SC Dose D, single IV Dose E, single SC Dose F, multiple SC Dose G, single IV Dose H, multiple SC Dose I (optional) and multiple SC Dose J (optional) of IMVT-1402 or placebo. IMVT-1402 and placebo are sterile SC or IV injections.

Previous interventions:
Participants will be randomized to receive either a single Intravenous (IV) Dose A, single IV Dose B, single subcutaneous (SC) Dose C, multiple SC Dose D, single IV Dose E, single SC Dose F, multiple SC Dose G, single IV Dose H, multiple SC Dose I (optional) and multiple SC Dose J (optional) of IMVT-1402 or placebo. IMVT-1402 and placebo is a sterile SC or IV injection.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

IMVT-1402

Primary outcome(s)

Current primary outcome measure as of 11/04/2025:
1. Part 1: Adverse events (AEs), serious adverse events (SAEs), and AEs leading to study treatment discontinuation measured using study records up to 13 weeks for SAD, up to 16 weeks for MAD, and 10 weeks for the alternative dose regimen cohort.
2. Part 2: AEs, SAEs, and AEs leading to study treatment discontinuation measured using study records for up to 16 weeks.
3. Part 3: AEs, SAEs, and AEs leading to study treatment discontinuation are measured using study records from Week 12 through Week 108.

Previous primary outcome measure from 11/03/2024 to 11/04/2025:
1. Part 1: Adverse events (AEs), serious adverse events (SAEs), and AEs leading to study treatment discontinuation measured using study records up to 13 weeks for SAD, up to 16 weeks for MAD, and 10 weeks for the alternative dose regimen cohort.
2. Part 2: AEs, SAEs, and AEs leading to study treatment discontinuation measured using study records up to 16 weeks.

Previous primary outcome measure from 04/12/2023 to 11/03/2024:
Adverse events (AEs), serious adverse events (SAEs), AEs leading to study treatment discontinuation measured using study records up to 13 weeks for SAD, up to 16 weeks for MAD, and 10 weeks for the alternative dose regimen cohort.

Previous primary outcome measure:
Adverse events (AEs), serious adverse events (SAEs), AEs leading to study treatment discontinuation measured using study records up to 13 weeks for SAD and up to 16 weeks for MAD

Key secondary outcome(s))

Current secondary outcome measures as of 11/03/2024:
1. Part 1 and Part 2: Serum concentrations of IMVT-1402 measured using blood samples will be collected up to Day 85 for Part 1 and up to Week 16 for Part 2. Pharmacokinetics will be analyzed using non-compartmental analysis.
2. Part 1 and Part 2: Serum concentrations of PD parameters including Total Immunoglobulin (IgG), IgG1, IgG2, IgG3 and IgG4 up to Day 85 for Part 1 and up to Week 16 for Part 2. Pharmacodynamics will be analyzed using the Pharmacodynamic analysis set (PDAS).
3. Part 1 and Part 2: Number of participants with treatment-emergent positive anti-drug antibodies (ADAs) and neutralizing antibodies (nAbs) up to Day 85 for Part 1 and up to Week 16 for Part 2. The ADA analysis will be based on the anti-drug antibodies analysis set (ADAAS).

Previous secondary outcome measures as of 23/05/2023 to 11/03/2024:
1. Serum concentrations of IMVT-1402 measured using blood samples will be collected up to Day 85. Pharmacokinetics will be analyzed using non-compartmental analysis.
2. Serum concentrations of PD parameters including Total Immunoglobulin (IgG), IgG1, IgG2, IgG3 and IgG4 up to Day 85. Pharmacodynamics will be analyzed using the Pharmacodynamic analysis set (PDAS).
3. Number of participants with treatment-emergent positive anti-drug antibodies (ADAs) and neutralizing antibodies (nAbs) up to Day 85. The ADA analysis will be based on the anti-drug antibodies analysis set (ADAAS).

Previous secondary outcome measures:
1. Serum concentrations of IMVT-1402 up to Day 85

2. Serum concentrations of PD parameters including Total Immunoglobulin (IgG), IgG1, IgG2, IgG3 and IgG4 up to Day 85
3. Number of participants with treatment-emergent positive anti-drug antibodies (ADAs) and neutralizing antibodies (nAbs) up to Day 85

Completion date
31/07/2028

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 11/03/2024:
Participants between the ages of 18 and 75 years will be included.

Previous participant inclusion criteria:
1. Have a body weight of ≥50 kg
2. Are willing and capable of giving written informed consent, which includes being able to comply with all aspects of the study treatment and testing schedule
3. Have adequate venous access, assessed at the time of screening, that allows for IV dosing and /or repeated phlebotomy
4. Are healthy as determined by the Investigator based on a medical evaluation including medical history, physical examination, laboratory tests, and Electrocardiogram (ECG).
5. Are female, not lactating, and of NCBP
6. Are male and have had a vasectomy >6 months prior to the Screening Visit or agree to use contraceptive methods starting at the Screening Visit and continuing throughout the study and for 90 days after the final study treatment administration

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
Current participant exclusion criteria as of 11/03/2024:
Not meeting the inclusion criteria.

Previous participant exclusion criteria:
1. Have any history or evidence of any clinically significant cardiovascular, gastrointestinal, endocrinologic, hematologic, hepatic, immunologic, metabolic, urologic, pulmonary, neurologic, dermatologic, psychiatric, renal, or other major disease, as judged by the Investigator.
2. Have an active malignancy or history of malignancy in the 3 years prior to the Screening Visit (exclusive of non-melanoma skin cancer, cervical cancer in situ or prostate cancer in situ) or any history of malignancy not deemed cured by adequate treatment.
3. Have any clinically significant history of allergic conditions, including drug allergies, anaphylactic reactions, or hypersensitivity to study treatments or components. Participants with currently asymptomatic, seasonal allergies or exercise-induced bronchospasm prior to study treatment administration are eligible.
4. Have undergone any blood loss or phlebotomy with removal of ≥500 milliliter (mL) of blood within 56 days prior to the Screening Visit.
5. Have received a transfusion of any blood or blood products within 56 days or donated plasma within 7 days prior to the Screening Visit.
6. Have participated in any other study involving an investigational product (IP) within the last 30 days or 5 half-lives, whichever is greater (6 months for anti-neonatal fragment crystallizable receptor [FcRn] therapy), prior to the Screening Visit or during the study.

Date of first enrolment
18/05/2023

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
New Zealand

Study participating centre
New Zealand Clinical Research OPCO Ltd
Grd Floor 3, Ferncroft St, Grafton
Auckland
New Zealand
1010

Study participating centre
New Zealand Clinical Research - Christchurch
264 Antigua Street
Christchurch, Canterbury
New Zealand
8011

Sponsor information

Organisation
Immunovant Sciences GmbH

Funder(s)

Funder type
Industry

Funder Name
Immunovant Sciences GmbH

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 23/05/2023:
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality reasons.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available