

A study in healthy volunteers to look at safety and tolerability of ALKS 4510

Submission date 06/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/05/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This clinical study assesses how safe and well-tolerated an investigational drug is in a healthy adult population.

Who can participate?

Healthy adults aged 18-55 years

What does the study involve?

Part 1 is designed to assess the effect of a single dose of ALKS 4510 in healthy participants. Participants will have three study visits, which include a screening, a treatment period with four consecutive overnight stays, and a safety follow-up.

Part 2 is designed to assess the effect of multiple daily doses of ALKS 4510 in healthy participants. Participants will have 3 study visits, which include a screening, a treatment period with 12 consecutive overnight stays and a safety follow-up.

What are the possible benefits and risks of participating?

This is a phase 1 healthy volunteer study, and participants will be administered the study drug for research purposes only. This trial may help reveal important scientific knowledge that could contribute to the development of a drug.

As with all interventional studies, the drug treatment may involve side effects. Participants will be carefully monitored for any side effects; however, not all of the side effects that the study drug may have are known.

Where is the study run from?

Alkermes, Inc. (USA). The study is conducted at a phase 1 clinical trial site in Australia

When is the study starting and how long is it expected to run for?

May 2025 to November 2025

Who is funding the study?
Alkermes, Inc. (USA)

Who is the main contact?
Clinicaltrials@alkermes.com

Contact information

Type(s)

Public, Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

ALKS 4510-101

Study information

Scientific Title

A randomized, double-blind, placebo-controlled, first-in-human study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ALKS 4510 in healthy subjects

Study objectives

Study to assess the safety, tolerability and pharmacokinetics of single-ascending and multiple-ascending doses of ALKS 4510

Ethics approval required

Ethics approval required

Ethics approval(s)

submitted 19/03/2025, Bellberry Human Research Ethics Committee (HREC) (123 Glen Osmond Road, Eastwood, 5063, Australia; +61 9 8361 3222; bbl@bellberry.com.au), ref: 2025-02-229

Study design

Single-centre randomized double-blind placebo-controlled study

Primary study design

Interventional

Study type(s)

Safety

Health condition(s) or problem(s) studied

Phase 1 study drug

Interventions

Part 1 SAD: Healthy volunteers will be randomized by using a randomization code to receive a single dose of oral ALKS 4510 or placebo for 1 day in each of five cohorts

Part 2 MAD: Healthy volunteers will be randomized by using a randomization code to receive one dose of oral ALKS 4510 or placebo every day for 10 consecutive days in each of four cohorts

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

ALKS 4510

Primary outcome(s)

Incidence of Treatment-Emergent Adverse Events by monitoring case report forms through dosing and safety follow up to 17 days

Key secondary outcome(s)

Levels of ALKS 4510 in blood measured as C_{max}, T_{max} (Day 1), AUC (over 12 hours), T-half, CL/F, and V_z/F using pharmacokinetic non-compartmental methods at 3 study visits with duration of participation of about 17 days

Completion date

30/11/2025

Eligibility

Key inclusion criteria

1. Participants must be 18 to 55 years of age, inclusive, at the time of informed consent
2. Willing and able to provide informed consent before study participation
3. Has a BMI ≥ 18 and ≤ 30 kg/m²
4. Is overtly healthy as determined by medical evaluation, including medical history, physical examination, laboratory tests, vital signs, and safety ECGs
5. Must adhere to contraceptive use

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

55 years

Sex

All

Key exclusion criteria

1. Subjects who have demonstrated allergic reactions (eg, food, drug, atopic reactions, or asthmatic episodes) which, in the opinion of the Investigator, interfere with their ability to participate in the study
2. The subject has poor peripheral venous access
3. Clinically significant illness or disease (eg, psychiatric disorders, disorders of the gastrointestinal tract, liver, kidney, respiratory system, endocrine system, hematological system, neurological system (including any sleep disorder such as sleep apnea or narcolepsy), or cardiovascular system, infection, visual conditions, or subjects who have a congenital abnormality in metabolism)
4. Any history at Screening of gastrointestinal or renal surgery that may affect PK profiles of ALKS 4510 (eg, hepatectomy, nephrectomy, digestive organ resection, or surgery that alters the gastrointestinal tract without resection), or other conditions that may impact absorption (malabsorption syndrome, inflammatory bowel disease, etc). Uncomplicated appendectomy and /or hernia repair are allowed
5. Is currently pregnant or breastfeeding, or is planning to become pregnant during the study

Date of first enrolment

12/05/2025

Date of final enrolment

30/11/2025

Locations

Countries of recruitment

Australia

Study participating centre**Scientia Clinical Research Limited**

Bright Building, Level 5

Corner High and Avoca Street

Randwick

Australia

2031

Sponsor information

Organisation

Alkermes (United States)

ROR

<https://ror.org/038hqfn26>

Funder(s)

Funder type

Industry

Funder Name

Alkermes

Alternative Name(s)

Alkermes plc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Ireland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as they are intellectual property

IPD sharing plan summary

Not expected to be made available