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

Submission date
06/05/2025

Recruitment status
No longer recruiting

Registration date
20/05/2025

Overall study status
Completed

Last Edited
19/05/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Public, Scientific

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Additional identifiers

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

Primary study design
Interventional

Study design
Single-centre randomized double-blind placebo-controlled study

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 Cmax , Tmax (Day 1), AUC (over 12 hours), T-half, CL /F, and Vz/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
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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