ISRCTN46120216 https://doi.org/10.1186/ISRCTN46120216

A study to evaluate safety and tolerability of ALKS 7290 in healthy participants and in attention deficit hyperactivity disorder

Submission date
19/08/2026

Recruitment status
No longer recruiting

Registration date
24/08/2026

Overall study status
Completed

Last Edited
21/08/2026

Condition category
Mental and Behavioural Disorders

[ ] 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
This is a clinical study to assess how safe and well tolerated an investigational drug (ALKS 7290) is in healthy adults and adults with attention deficit hyperactivity disorder (ADHD), as well as to understand how food impacts the absorption of ALKS 7290.

Who can participate?
Part 1 (SAD) and Part 2 (MAD): healthy adults aged 18-55 years
Part 3 (ADHD): ADHD patients aged 18 to 50 years

What does the study involve?
Part 1 Single Ascending Dose (SAD):
There will be six groups of people who will randomized to receive one dose of ALKS 7290 or placebo. Each participant will receive one dose and will be monitored in clinic and then followed after receiving the dose to monitor safety and side effects.
Part 1 SAD3a/b:
There will be two groups of participants who will receive ALKS 7290 with food and those who will receive ALKS 7290 without food. After dosing participants will stay at the clinic for monitoring.
Part 2 Multiple Ascending Dose (MAD):
There will be four groups of people and they will be randomized on ALKS 7290 and placebo. Participants will receive two doses each day for 10 days and will stay in clinic for 13 days to be closely monitored.
Part 3 ADHD:
Patients with ADHD will be randomized to ALKS 7290 or placebo. Neither the patient nor the study staff know who is receiving ALKS 7290 or placebo. Participants will take the study drug or placebo daily for 2 weeks and will be monitored for 7 days after treatment.

What are the possible benefits and risks of participating?
This is a Phase I 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 risks that are known as well as risks that are currently unknown. 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)

When is the study starting and how long is it expected to run for?
October 2025 to August 2026

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

Who is the main contact?
Clinical Operations Manager, clinicaltrials@alkermes.com

Contact information

Type(s)
Public, Scientific

Contact name
Mr Clinical Trial Manager

Contact details
900 Winter St
Waltham
United States of America
02451
+1 (0)888-235-8008
clinicaltrials@alkermes.com

Type(s)
Principal investigator

Contact name
Dr David Walling

Contact details
3771 Katella Ave #300
Los Alamitos
United States of America
90720
+1 (0)5627427116
contactus@cenexel.com

Additional identifiers

Study information

Scientific Title
A multi-part, randomized, double-blind, placebo-controlled, first-in-human study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and food effect of ALKS 7290 in healthy participants and participants with attention deficit hyperactivity disorder

Acronym
ALKS 7290-101

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 25/09/2025, Advarra (6100 Merriweather Dr., Suite 600, Columbia, 21044, United States of America; +1 (0)4108842900; cirbi@advarra.com), ref: Pro00090262

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
Attention deficit hyperactivity disorder (ADHD)

Interventions
Part 1 Single Ascending Dose (SAD):
There will be six groups of people who will randomized to receive one dose of ALKS 7290 or placebo by oral administration. Each participant will receive one dose and will be monitored in clinic and then followed after receiving the dose to monitor safety and side effects.

Part 1 SAD3a/b:
There will be two groups of participants who will receive ALKS 7290 with food and those who will receive ALKS 7290 without food. After dosing participants will stay at the clinic for monitoring.

Part 2 Multiple Ascending Dose (MAD):
There will be four groups of people and they will be randomized on ALKS 7290 and placebo. Participants will receive two doses each day for 10 days and will stay in clinic for 13 days to be closely monitored.

Part 3 ADHD:
Patients with ADHD will be randomized to ALKS 7290 or placebo. Neither the patient nor the study staff know who is receiving ALKS 7290 or placebo. Participants will take the study drug or placebo daily for 2 weeks and will be monitored for 7 days after treatment.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
ALKS 7290

Primary outcome(s)
1. Part 1, 2, 3 (ADHD): Safety and tolerability of ALKS 7290 measured using the incidence of treatment-emergent adverse events at up to 17 days

2. Part 1 (SAD Cohort Food Effect): Food effect of ALKS 7290 in healthy participants measured using Cmax and Tmax at up to 15 days (ADHD) and 17 days (Part 2)

Key secondary outcome(s)
1. Part 2, 3 (ADHD): Plasma pharmacokinetics of ALKS 7290 measured using Cmax, Tmax, Tlag, AUC at up to 14 days

Completion date
19/08/2026

Eligibility

Key inclusion criteria
Part 1 (single ascending dose [SAD]) and Part 2 (multiple ascending dose [MAD]):
1. Male or female between 18 to 55 years of age, inclusive, at the time of informed consent
2. Has a body mass index (BMI) ≥18 and ≤30 kg/m2
3. Is healthy as determined by medical evaluation

Part 3 (ADHD):
1. Is 18 to 50 years of age at time of informed consent
2. Meets Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) criteria for ADHD
3. Is healthy as determined by medical evaluation

4. Has a BMI within 18 to 38 kg/m2 at Screening
5. Willing to discontinue any medications for management of ADHD at least 14 days prior to enrollment and for study duration

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
138

Key exclusion criteria
Part 1 (SAD) and Part 2 (MAD):
1. The participant has a known hypersensitivity to any component of the formulation of ALKS 7290
2. The participant has a clinically significant illness or disease
3. History or presence of clinically significant acute or chronic liver disease positive urine drug screen at check-in, and/or positive alcohol test result upon admission
4. Has active suicidal ideation or any history of suicidal behavior; a Columbia-Suicide Severity Rating Scale (C-SSRS) suicidal ideation score of 4 or 5 at Screening or admission, or for the period within 12 months before Screening
5. Use of prescription medications within 2 weeks prior to admission or use of nonprescription medications, herbal and nutritional supplements, with the exception of topical medications, within 1 week prior to admission

Part 3 (ADHD):
1. The participant has a known hypersensitivity to any component of the formulation of ALKS 7290
2. The participant has a clinically significant illness or disease
3. Has any clinically abnormal symptom or organ impairment, as judged by the Investigator
4. Has a history or presence of clinically significant acute or chronic liver disease
5. Has a positive urine drug screen at check-in
6. History of clinically significant arrhythmia or uncontrolled arrhythmia
7. Has a significant neurological disorder, including dementia, neurodegeneration, stroke, epilepsy or seizures
8. Meets DSM-5 criteria for a major depressive episode in the last 12 months
9. Participant poses a current suicide risk as assessed by the Investigator or as confirmed by the Baseline/Screening version of the C-SSRS
10. Is treatment resistant (as defined by having failed two attempts of standard treatments for ADHD)

Date of first enrolment
22/10/2025

Date of final enrolment
17/07/2026

Locations

Countries of recruitment
United States of America

Sponsor information

Organisation
Alkermes (United States)

ROR
https://ror.org/038hqfn26

Funder(s)

Funder type

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

IPD sharing plan summary

Not expected to be made available