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COMPLETED 

Phase 1 Safety Study of ALK-001 in Healthy Volunteers

ClinicalTrials.gov ID  NCT02230228

Sponsor  Alkeus Pharmaceuticals, Inc.

Information provided by  Alkeus Pharmaceuticals, Inc. (Responsible Party)

Last Update Posted  2015-03-24

Study Details Tab

Study Overview

Brief Summary

This protocol is a phase 1 clinical study to assess the safety and pharmacokinetics of ALK-001 in healthy volunteers. Please contact trials@alkeus.com for any questions.

Official Title

A Phase 1, Open Label, Repeat Dose Study to Investigate the Safety and Pharmacokinetics of 4-week Daily Dosing of ALK-001 in Healthy Volunteers

Conditions

Stargardt Disease

Age-related Macular Degeneration

Other Retinal Dystrophies

Intervention / Treatment

- Drug: ALK-001 (No generic name)



Other Study ID Numbers ⓘ

- ALK001-P1001

Study Start ⓘ

2014-04

Primary Completion (Actual) ⓘ

2014-09

Study Completion (Actual) ⓘ

2015-02

Enrollment (Actual) ⓘ

40

Study Type ⓘ

Interventional

Phase ⓘ

Phase 1

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](https://medlineplus.gov/genetics/) (https://medlineplus.gov/genetics/) related topics:

[Stargardt macular degeneration](https://medlineplus.gov/genetics/condition/stargardt-macular-degeneration) (https://medlineplus.gov/genetics/condition/stargardt-macular-degeneration). [Age-related macular degeneration](https://medlineplus.gov/genetics/condition/age-related-macular-degeneration) (https://medlineplus.gov/genetics/condition/age-related-macular-degeneration).

[MedlinePlus](https://medlineplus.gov/) (https://medlineplus.gov/) related topics: [Safety](https://medlineplus.gov/safety.html) (https://medlineplus.gov/safety.html).

[Genetic and Rare Diseases Information Center](https://rarediseases.info.nih.gov/gard) (https://rarediseases.info.nih.gov/gard) resources: [Stargardt Disease](https://rarediseases.info.nih.gov/diseases/181/stargardt-disease) (https://rarediseases.info.nih.gov/diseases/181/stargardt-disease).

[FDA Drug and Device Resources](https://www.clinicaltrials.gov/fda-links) (https://www.clinicaltrials.gov/fda-links).

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

No location data

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://www.clinicaltrials.gov/study-basics/learn-about-studies) (<https://www.clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Main Inclusion Criteria

- Adult between 21 and 70 years old (inclusive)
- Healthy subject, as judged by investigator
- Subject is able and willing to comply with study requirements (study medication compliance, schedule of follow-up visits)
- Subject has provided informed consent to participate
- If female, subject uses a medically accepted birth control method and agrees to use such a method for entire clinical trial period

Main Exclusion Criteria:

- Subject has taken disallowed items during the past 30 days
- Female with a positive urine pregnancy test at screening
- Lactating woman
- Subject has participated in any clinical study involving an investigational drug, biologic or device, during the past 30 days
- History or current evidence of gastrointestinal malabsorption
- Subject has any other medical condition, which in the opinion of the investigator, is likely to prevent compliance with protocol and/or interfere with successful collection of study
- Subject has, in the opinion of investigator, clinically significant laboratory result(s), positive drug or alcohol screening, or ECG, which makes subject unsuitable for participation.

Ages Eligible for Study ⓘ

21 Years to 70 Years (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Basic Science

Allocation ⓘ : N/A

Interventional Model ⓘ : Single Group Assignment

Masking ⓘ : None (Open Label)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: ALK-001 capsules	Drug: ALK-001 (No generic name) - Daily, oral administration of ALK-001 capsules. - Other Names: - C20-D3-Retinyl Acetate - C20 Deuterated vitamin A

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Safety of 4-week daily dosing of ALK-001 in healthy adults.	Safety evaluations combine: adverse events (AE), laboratory testing (hematology and biochemistry panels), 12-lead electrocardiograms (ECGs), vital signs, physical examination, and visual function (visual acuity and a self-reported questionnaire).	4 weeks

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Alkeus Pharmaceuticals, Inc.

Investigators ⓘ

- Study Director: Leonide Saad, PhD, Alkeus Pharmaceuticals, Inc.
- Study Chair: Ilyas Washington, PhD, Columbia University

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2014-08-27

First Submitted that Met QC Criteria ⓘ

2014-09-02

First Posted (Estimated) ⓘ

2014-09-03

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2015-03-21

Last Update Posted (Estimated) ⓘ

2015-03-24

Last Verified ⓘ

2015-03

More Information

Terms related to this study

Additional Relevant MeSH Terms

Retinal Degeneration
Retinal Diseases
Eye Diseases
Eye Diseases, Hereditary
Genetic Diseases, Inborn
Macular Degeneration
Retinal Dystrophies
Stargardt Disease
Vitamins
Micronutrients
Physiological Effects of Drugs
Protective Agents
Anticarcinogenic Agents
Antineoplastic Agents
Adjuvants, Immunologic
Immunologic Factors
Vitamin A
Retinol acetate