Multiple ascending dose study of ALKS 7119

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27126

Source
Nationaal Trial Register

Health condition

Proof of pharmacology

Sponsors and support

Primary sponsor: Alkermes, Inc.
Source(s) of monetary or material Support: Alkermes, Inc.

Intervention

Outcome measures

Primary outcome

Safety: Evaluation of safety will be based on the occurrence of adverse events (AEs), vital signs, results of clinical laboratory tests electrocardiogram (ECG) parameters, real-time ECG parameters. Reported AE terms will be coded using the Medical Dictionary for Regulatory Activities (MedDRA® version 19.0 or higher) preferred terms and system organ classes.

Secondary outcome

N/A

Study description

Background summary

Subjects will be recruited in The Netherlands

Study design

PK

•Area under the concentration-time curve from time zero to the last quantifiable time interval (AUClast) on Day 1 & 14

•Cmax, Area under the concentration-time curve over the 24-hour dosing interval (AUC24h), time to Cmax (tmax) and terminal elimination half-life (t½) of ALKS 7119 on Day 1 & 14

•Area under the concentration-time curve from time zero to infinity (AUC∞) after the first dose on Day 1

•Trough plasma concentration (Ctrough) on Day 1 through 14
•Accumulation ratio (Day 14/Day 1 AUC24h ratio)

Intervention

The subjects will receive multiples doses of ALK 7119 or placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Willing and able to provide informed consent

2. Capable of understanding and complying with the protocol

3. Male or female adult and ≥18 and ≤45 years of age, inclusive, at screening (Visit 1)

4. Has a body mass index ≥18.0 and ≤32.0 kg/m2 at screening (Visit 1)

5. Agrees to use an acceptable method of contraception from 30 days prior to screening and for 90 days after any study drug administration, or must be surgically sterile or post-menopausal (if female)

Exclusion criteria

1. Clinically significant medical condition or observed abnormalities, in the opinion of the investigator (including, clinically significant physical examination finding, vital sign result, ECG result, laboratory or urinalysis test result) and/or any other finding that, in the investigator's judgment, could potentially compromise subject safety, or PK or PD evaluation, or affect the subject's ability to adhere to the protocol visit schedule, or fulfill visit requirements

2. Female subject that is currently pregnant or breastfeeding, or plans to become pregnant or begin breastfeeding at any point during the study and for 90 days after any study drug administration

3. Has a history of intolerance or hypersensitivity to dextromethorphan or any dextromethorphan-containing product

4. Has had a clinically significant illness in the 30 days prior to first study drug administration (Day 1)

5. Has a positive drug screen

6. Has a positive breath test for alcohol at screening (Visit 1) or upon admission (Day -1)

7. Has a positive serology test for hepatitis B virus surface antigen (HBsAg), hepatitis B virus core antibody (HBcAb), hepatitis C virus antibody (HCVAb), or human immunodeficiency virus antibody (HIVAb) at screening (Visit 1)

8. Has a clinically significant lifetime history of suicidal ideation or suicidal behavior and/or poses a current (within past year) suicide risk, as

9. Has used any prescription or over-the-counter medication, including herbal remedies and nutritional supplements (except vitamins), within 7 days prior to screening (Visit 1) or admission (Day -1)

10. Has ingested any alcohol, caffeine or xanthine within 24 hours prior to inpatient admission (Day -1), or excessive caffeine consumption (defined as ≥800 mg per day) at screening (Visit 1)

11. Has used any product containing nicotine within 30 days prior to admission (Day -1)

12. Has participated in a clinical trial of an investigational product within 3 months prior to screening (Visit 1) or participated in more than four investigational drug studies within 1 year prior to screening (Visit 1)

13. Has previously participated in a clinical trial with ALKS 7119

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-07-2016
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5801
NTR-old	NTR5956
Other	: ALK7119-A103

Study results