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A trial to learn about a study drug (STAR-0215) in adults with hereditary angioedema

Submission date
10/02/2023

Recruitment status
No longer recruiting

Registration date
23/04/2024

Overall study status
Completed

Last Edited
29/05/2025

Condition category
Circulatory System

[ ] 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:
Astria Therapeutics, Inc. is sponsoring this research study to evaluate the safety and tolerability (how tolerable any side effects are) of the investigational drug STAR-0215, in patients with hereditary angioedema (HAE).
HAE is a rare genetic disorder that causes repeated and unpredictable attacks of swelling in the face, arms and legs, abdomen, genitals and airway. These attacks can be severe, painful, disabling and life threatening. Although there are approved medications for HAE, patients' different responses to the approved medications often require frequent dosing and may leave gaps when patients are not protected against HAE attacks. The ultimate goal is to provide a safe and effective preventative treatment that is dosed infrequently to decrease the burden of disease for patients with HAE.
In HAE, the blood protein plasma kallikrein has been shown to be overactive. STAR-0215 blocks the activity of this protein and may therefore prevent attacks in patients with HAE. STAR-0215 may have a longer activity in the blood stream compared to other medicines that are currently approved for use in HAE, which may mean that it could provide longer activity against plasma kallikrein and may be administered less frequently.

Who can participate?
About 28 participants with HAE will take part in the trial globally.

What does the study involve?
In this trial, participants will be assigned to one of the following groups:
Group 1: a single dose of STAR-0215 via injection under the skin
Group 2: two doses of STAR-0215 via injection under the skin; an initial dose followed by another dose 84 days (about 3 months) later.
Group 3: two doses of STAR-0215 via injection under the skin; an initial dose followed by another dose 28 days (about 1 month) later.

Participants can take on-demand medicines if they have HAE attacks during the trial.

There will be a screening period to confirm eligibility, and a treatment period. For participants who are willing and eligible to consent, they can begin participation in a long-term open label

extension (STAR-0215-202). Upon enrollment in STAR-0215-202, participants will continue to receive STAR-0215 and be monitored according to the procedures defined in that protocol. For participants who do not enroll in the long-term open label extension study, monitoring will be performed through 16 months after the last dose of STAR-0215 in all groups. Participants will undergo various tests and procedures such as: blood and urine tests, ECGs, vital signs and questionnaires.

What are the possible benefits and risks of participating?
There may not be a direct medical benefit from receiving the study drug. Participants HAE may get better, stay the same, or even get worse.
It is possible that the results may not help individuals but the information we get from this study will help us improve treatment for people with HAE in the future.

Where is the study run from?
Astria Therapeutics, Inc. (USA)

When is the study starting and how long is it expected to run for?
February 2023 to September 2025

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

Who is the main contact?
Dr Patrick Yong, patrick.yong@nhs.net

Study website
https://astriatx.com/for-patients/alpha-star-trial/

Contact information

Type(s)
Scientific

Contact name
Dr Clinical Trial Inquiries Astria Therapeutics, Inc

Contact details
22 Boston Wharf Road
10th Floor
Boston MA
United States of America
02210
+1 617 349 1971
201Study_General@astriatx.com

Type(s)
Principal Investigator

Contact name
Dr Patrick Yong

Contact details
Frimley Park Hospital
Portsmouth Road
Frimley
United Kingdom
GU16 7UK
+44 1276 604 604
patrick.yong@nhs.net

Additional identifiers

EudraCT/CTIS number
2022-502953-32

IRAS number
1007328

ClinicalTrials.gov number
NCT05695248

Secondary identifying numbers
STAR-0215-201, IRAS 1007328, CPMS 55306

Study information

Scientific Title
A phase 1b/2 single and multiple dose study to assess the safety, tolerability, clinical activity, pharmacokinetics, pharmacodynamics, and immunogenicity of STAR-0215 in participants with hereditary angioedema (The ALPHA-STAR Trial)

Acronym
The ALPHA-STAR Trial

Study objectives
Primary objectives:
To assess the safety and tolerability of subcutaneous (SC) administration of single and multiple doses of STAR-0215 in participants with Type I or Type II HAE.

Secondary objectives:
1. To assess the efficacy of SC administration of single and multiple doses of STAR-0215 in participants with Type I or Type II HAE
2. To characterize the pharmacokinetics (PK) of SC administration of single and multiple doses of STAR-0215 in participants with Type I or Type II HAE
3. To characterize the pharmacodynamics (PD) of SC administration of single and multiple doses of STAR-0215 in participants with Type I or Type II HAE
4. To assess the immunogenicity of SC administration of single and multiple doses of STAR-0215 in participants with Type I or Type II HAE

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/09/2023, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8269; cambsandherts.rec@hra.nhs.uk), ref: 23/EE/0055

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice, Hospital, University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Hereditary angioedema (HAE)

Interventions
In this trial, participants will be assigned to one of the following groups:
Group 1: a single dose of STAR-0215 via subcutaneous injection
Group 2: two doses of STAR-0215 via subcutaneous injection; an initial dose followed by another dose 84 days (about 3 months) later.
Group 3: two doses of STAR-0215 via subcutaneous injection; an initial dose followed by another dose 28 days (about 1 month) later.

Intervention Type
Drug

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
STAR-0215

Primary outcome measure
Number of Participants Experiencing Treatment-emergent Adverse Events [Time Frame: Day 1 through Day 448 (Cohort 1), Day 531 (Cohort 2), and Day 475 (Cohort 3)

Secondary outcome measures
1. Change From Baseline in Monthly HAE Attack Rate [Time Frame: Baseline through Day 168 (Cohort 1), Day 251 (Cohort 2), and Day 195 (Cohort 3)]

2. Severity of HAE Attacks Experienced by Participants [Time Frame: Cohort 1: Day 1 through Day 168; Cohort 2: Day 1 through Day 251; Cohort 3: Day 1 through Day 195]
All HAE attacks will be classified according to severity (mild, moderate, and severe).
3. Duration of HAE Attacks [Time Frame: Cohort 1: Day 1 through Day 168; Cohort 2: Day 1 through Day 251; Cohort 3: Day 1 through Day 195]
Duration will be reported as shorter than 12 hours, 12 to 24 hours, 24 to 48 hours, and longer than 48 hours.
4. Number of Participants Experiencing HAE Attacks Requiring On-demand Therapy [Time Frame: Cohort 1: Day 1 through Day 168; Cohort 2: Day 1 through Day 251; Cohort 3: Day 1 through Day 195]
5. Time to First HAE Attack After First and Last Dosing [Time Frame: Cohort 1: Day 1 through Day 168; Cohort 2: Day 1 through Day 251; Cohort 3: Day 1 through Day 195]
6. Serum Concentration of STAR-0215 [Time Frame: Cohort 1: Day 1 (pre-dose, 4 hours post dose) up to Day 168; Cohort 2: Days 1 and 84 (pre-dose, 4 hours post dose) up to Day 251; Cohort 3: Days 1 and 28 (pre-dose, 4 hours post dose) up to Day 195]
Blood samples will be collected to measure the serum concentration of STAR-0215 before and after study drug administration.
7. Plasma Levels of Cleaved High-molecular-weight Kininogen [Time Frame: Cohort 1: Day 1 (pre-dose, 4 hours post dose) up to Day 168; Cohort 2: Days 1 and 84 (pre-dose, 4 hours post dose) up to Day 251; Cohort 3: Days 1 and 28 (pre-dose, 4 hours post dose) up to Day 195]
Blood samples will be collected to measure the plasma levels of cleaved high-molecular-weight kininogen (a measure of plasma kallikrein activity).
8. Number of Participants with Anti-drug Antibodies to STAR-0215 [Time Frame: Cohort 1: Day 1 (pre-dose); Days 14, 28, 56, 84, 112, 140, and 168; Cohort 2: Days 1 and 84 (pre-dose); Days 14, 28, 56, 111, 167, and 251; Cohort 3: Days 1 and 28 (pre-dose); Days 14, 55, 111, and 195]
Blood samples will be collected to assess the formation of STAR-0215 anti-drug antibodies in serum before and after study drug administration.

Overall study start date
06/02/2023

Completion date
13/03/2025

Eligibility

Key inclusion criteria
1. Documented diagnosis of HAE (type I or II). The following must be met: Documented clinical history consistent with HAE (for example, subcutaneous or mucosal, nonpruritic swelling episodes without accompanying urticaria).
2. Experienced at least 2 HAE attacks during the Run-In period, as confirmed by an investigator based on meeting the protocol-specified definition of an HAE attack.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
28

Total final enrolment
29

Key exclusion criteria
1. Any concomitant diagnosis of another form of chronic angioedema, such as acquired C1 inhibitor deficiency, HAE with normal C1-INH (also known as HAE type III), idiopathic angioedema, or angioedema associated with urticaria.
2. Use of therapies prescribed for the prevention of HAE attacks prior to Screening:
2.1. lanadelumab within 90 days
2.2. berotralstat within 21 days
2.3. all other prophylactic therapies, within 7 days
3. Any exposure to angiotensin-converting enzyme inhibitors or any estrogen containing medications with systemic absorption (such as hormonal contraceptives or hormone replacement therapy) within 28 days prior to Screening.
4. Any exposure to androgens (for example, stanozolol, danazol, oxandrolone, methyltestosterone, testosterone) within 7 days prior to Screening.

Date of first enrolment
21/02/2023

Date of final enrolment
01/07/2024

Locations

Countries of recruitment
Bulgaria

Canada

Czech Republic

England

Germany

Poland

United Kingdom

United States of America

Study participating centre
St James's Hospital
Leeds Teaching Hospitals NHS Trust

Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Addenbrooke's Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Astria Therapeutics, Inc

Sponsor details
22 Boston Wharf Road
10th Floor
Boston
United States of America
MA 02210
(+1) 617 349 ext 1971
201Study_General@astriatx.com

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Astria Therapeutics, Inc.

Results and Publications

Publication and dissemination plan
Peer reviewed scientific journals
Conference presentation
Publication on website
Other publication
Submission to regulatory authorities
Coded study data will be shared via secure Sponsor systems. Data sharing will be in accordance with current data privacy legislation and restricted to authorised parties with the necessary confidentiality agreements in place.

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date