A multicenter, international, randomized, placebo controlled, double-blind, parallel group and event driven Phase 3 study of the oral FXIa inhibitor asundexian (BAY 2433334) for the prevention of ischemic stroke in male and female participants aged 18 years and older after an acute non-cardioembolic ischemic stroke or high-risk TIA

Published: 29-11-2022
Last updated: 05-10-2024

This study has been transitioned to CTIS with ID 2023-503793-20-00 check the CTIS register for the current data. The main purpose of this study is to learn whether asundexian works better than placebo at reducing ischemic strokes in participants who...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Embolism and thrombosis
Study type	Interventional

Summary

ID

NL-OMON51380

Source
ToetsingOnline

Brief title
OCEANIC-STROKE

Condition

- Embolism and thrombosis

Synonym
ischemic stroke, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer

Intervention

Keyword: Asundexian, stroke

Outcome measures

Primary outcome

- ischemic stroke.

- ISTH major bleeding.

Secondary outcome

- All strokes (ischemic and hemorrhagic)

- Composite of CV death, MI or stroke

- Composite of all-cause mortality, MI or stroke

- Disabling stroke (mRS >=3 at 90 days)

- All-cause mortality

- Transient ischemic attack (TIA)

- Composite of ISTH major or clinically relevant non-major bleeding

- ISTH clinically relevant non-major bleeding

- Symptomatic intracranial hemorrhage

- Hemorrhagic stroke

- Fatal bleeding

- Minor bleeding

- Composite of ischemic stroke or ISTH major bleeding

- Composite of CV death, all stroke, MI or ISTH major bleeding

- Composite of all-cause mortality, disabling stroke, fatal bleeding,

symptomatic intracranial hemorrhage

Study description

Background summary

Researchers are looking for a better way to prevent an ischemic stroke. People who already had a non-cardioembolic stroke are more likely to have another stroke. This is why they are treated preventively with an antiplatelet therapy, the current standard of care. Anticoagulants are another type of medicine that prevents blood clots. The study treatment asundexian is a new type of anticoagulant currently under development to provide further treatment options.

Study objective

This study has been transitioned to CTIS with ID 2023-503793-20-00 check the CTIS register for the current data.

The main purpose of this study is to learn whether asundexian works better than placebo at reducing ischemic strokes in participants who recently had a non-cardioembolic ischemic stroke or high-risk TIA when given in addition to standard antiplatelet therapy. Another aim is to compare the occurrence of major bleeding events during the study between the asundexian and the placebo group.

Study design

A multicenter, international, randomized, placebo controlled, double-blind, parallel group, event driven phase 3 study.

Intervention

- asundexian (once daily, oral)
- placebo (once daily, oral)

Study burden and risks

Dependent on the treatment group, the participants will either take asundexian or placebo for at least 3 months up to 31 months. Approximately every 3 months during the treatment period, either a phone call or a visit to the study site is scheduled on an alternating basis. During the study, the following procedures will be done: vital signs check such as blood pressure and heart rate, ECG, blood sampling and the participants will be asked to complete a questionnaire on quality of life.

Contacts

Public
Bayer

Siriusdreef 36
Hoofddorp 2132WT
NL
Scientific
Bayer

Siriusdreef 36
Hoofddorp 2132WT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Participants must be >= 18 years of age
2. Acute non-cardioembolic stroke or high-risk TIA
3. Systemic or cerebrovascular atherosclerosis or acute non-lacunar infarct

Exclusion criteria

1. Ischemic stroke <= 7 days before the index stroke event
2. Index stroke following procedures or strokes due to other rare causes
3. History of atrial fibrillation/flutter, left ventricular thrombus, mechanic valve or other cardioembolic source of stroke requiring anticoagulation

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2023
Enrollment:	105
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	nvt

Generic name:	Asundexian

Ethics review

Approved WMO Date:	29-11-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-01-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-03-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EU-CTR	CTIS2023-503793-20-00
EudraCT	EUCTR2022-001067-27-NL
CCMO	NL82515.056.22