

Study of a new medical device to treat brain aneurysms

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
14/01/2020	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
16/01/2020	Ongoing	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
16/12/2025	Circulatory System	<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The study aims to evaluate the safety and effectiveness of a new device to treat brain aneurysms.

Who can participate?

Patients with intracranial aneurysm

What does the study involve?

The study involves treatment with a minimally invasive device and a follow-up visit

What are the possible benefits and risks of participating?

Potential benefits include aneurysm healing. Like in any surgical intervention, there are possible procedure-related risks. A complete list is presented to subjects before enrollment.

Where is the study run from?

The General Hospital of Fortaleza (Brazil)

When is the study starting and how long is it expected to run for?

January 2020 to April 2026

Who is funding the study?

EndoStream Medical Ltd

Who is the main contact?

Danel Mayer, CEO

danel@endostream.com

Contact information

Type(s)

Public

Contact name

Mr Danel Mayer

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CLD219

Study information

Scientific Title

Nautilus endovascular device for wide neck cerebral aneurysm embolization study

Acronym

NEW

Study objectives

Safety and effectiveness of the investigational device.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 16/11/2019, Hospital Geral de Fortaleza/SUS (Government Unified Health System) (Rua Avila Goulart, nº 900, Fortaleza, 60.155-290, Brazil; +55 (85) 3101-7078; cephgf.ce@gmail.com), ref: 3.708.271

Approved 16/ 11/2019, Hospital Geral de Fortaleza Ethics Committee (Comitê de Ética do Hospital Geral de Fortaleza,

Rua Avila Goulart, nº 900 - Fortaleza - CE - Brazil, 60.155-290; Tel: +55 (85)3101-7078; Email: cephgf.ce@gmail.com), approval number: 3.708.271, EC ID number: 23797919.1.0000.5040

Study design

Interventional single-arm study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cerebral aneurysm

Interventions

Patients will undergo a single intervention with the Nautilus Endovascular Device followed by treatment follow up at 6 months.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Nautilus Endovascular Device

Primary outcome(s)

Death or stroke in treated vascular territory measured using the NIH stroke scale at intervention and at 6 months follow-up

Key secondary outcome(s)

Rate of stable, successful aneurysm occlusion measured using the Raymond Roy Occlusion Classification at intervention and at 6 months follow-up

Completion date

30/04/2026

Eligibility

Key inclusion criteria

Patients who present with intracranial aneurysm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

0

Key exclusion criteria

Unstable neurological deficit

Date of first enrolment

01/09/2022

Date of final enrolment

30/06/2025

Locations

Countries of recruitment

Brazil

Israel

Study participating centre

Hospital Geral de Fortaleza
R. Ávila Goularte, 900 - Papicu
Fortaleza
Brazil
60150-160

Sponsor information

Organisation

EndoStream Medical Ltd

Funder(s)

Funder type

Industry

Funder Name

EndoStream Medical Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available