

# Study of a new medical device to treat brain aneurysms

<b>Submission date</b> 14/01/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/01/2020	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/06/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input 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 December 2025

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

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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; cepghf.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: cepghf.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

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/01/2020

**Completion date**

01/12/2025

**Eligibility**

**Key inclusion criteria**

Patients who present with intracranial aneurysm

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

50

**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

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**Sponsor type**  
Industry

**Website**  
endostream.com

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
EndoStream Medical Ltd

## **Results and Publications**

### **Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal. No additional documents are available at this time.

### **Intention to publish date**

01/12/2026

### **Individual participant data (IPD) sharing plan**

The data will be held by the Principal Investigator of the study until the product becomes commercially available.

### **IPD sharing plan summary**

Not expected to be made available