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Study of a new medical device to treat brain aneurysms

Submission date 14/01/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/01/2020	**Overall study status** Ongoing	
Last Edited 04/06/2024	**Condition category** Circulatory System	

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
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Contact information

Type(s)
Public

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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; 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

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
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Sponsor information

Organisation
EndoStream Medical Ltd

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Sponsor type
Industry

Website
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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