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A safety study of Neucrylate AN™ Liquid Embolic System for the treatment of cerebral berry aneurysms

Submission date	Recruitment status	[ ] Prospectively registered
08/09/2009	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
06/10/2009	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
11/05/2017	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Protocol No. VALOR 8002

Study information

Scientific Title
A prospective, non-randomised, open-label, multicenter safety study of Neucrylate AN™ Liquid Embolic System for the treatment of cerebral berry aneurysms

Study objectives
The primary objectives of this safety study are to assess the efficacy and composite safety-and-efficacy of Neucrylate AN™ Liquid Embolic System for the treatment of cerebral aneurysms. The secondary objectives assess other features of the treatment, including the incidence of all AEs, an assessment of the passage of unwanted device into the arterial lumen, the user acceptability of the device, the success of delivery, need for retreatment, and neurologic deterioration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Germany: Medical Faculty of the University Duisberg, Essen Ethics Committee, approved on 05/05/2009 (ref: 09-4030)
2. United Kingdom: Scotland A Research Ethics Committee, approved on 05/08/2009 (ref: 09/MRE00/47)
3. Hungary: To be submitted as of 08/09/2009

Study design
Single-arm interventional study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Berry aneurysms in the brain

Interventions
The treatment being studied is the Neucrylate AN™ Liquid Embolic System, which is a liquid that is placed into the aneurysm via angiography catheters. There is no comparator. There are follow-up visits at 6 weeks and at 5 months following hospital discharge. All hospital visits and all follow-up visits include neurological assessments and adverse events/serious adverse events (AE/SAE) collection. The 6-month visit includes brain imaging (computed tomography angiography [CTA], magnetic resonance imaging [MRI]) or catheter angiography to assess the aneurysm.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Neurological assessments will be done using the Glasgow Coma Scale, Hunt and Hess Scale, and Modified Rankin Score. These will be done at Screening, Procedure Day, Post-procedure Day 1, Hospital Discharge, Week 6, and at the Month 6 Visit.
2. Aneurysm filling will be assessed using the following scale on Procedure Day and at the Month 6 Visit:
i. 0 - 24% filling
ii. 25 - 49% filling

iii. 50 - 74% filling
iv. 75 - 89% filling
v. 90% filling or more
3. Major Adverse Events (MAEs): During the implant procedure and for the 6-month follow-up period, all of the deaths, major strokes (resulting in a Modified Rankin score of >=3), and haemorrhages from the treated aneurysm will be documented.

Key secondary outcome(s))
1. Adverse Events (AEs) and Serious Adverse Events (SAEs): During the implant procedure and for the 6-month follow-up period, all of the adverse events and serious adverse events will be documented. The investigator will provide his/her opinion, based on clinical experience and judgment, on the relationship between the event and either: (a) the procedure done to implant Neucrylate™, or (b) the presence of the Neucrylate™ in the body.
2. Unwanted device: Unwanted passage of device beyond the aneurysm in the parent vessel, or prior to reaching the aneurysm, on a 6-point scale:
i. No device in brain arteries noted
ii. Device in brain arteries that compromise <=25% of the arterial lumen
iii. Device in brain arteries that compromise 26-50% of the arterial lumen
iv. Device in brain arteries that compromise 51-75% of the arterial lumen
v. Device in brain arteries that compromise >=75% of the arterial lumen
vi. Device completely occludes arterial lumen
3. User acceptability: For all three user acceptability measures (1) visibility of material, (2) ease of introduction, and (3) ease of delivery, assessments will be recorded.

Completion date
01/04/2011

Eligibility

Key inclusion criteria
1. Subject must be a male or female >=18 years of age (i.e., not children as defined by local law or regulation)
2. Subject must have a cerebral aneurysm and neurological status
3. Subject must be considered by the physician to be available for subsequent visits
4. Subject must be able to comply with all aspects of the treatment and evaluation schedule over 7 months duration
5. Subject must sign and date an EC/IRB-approved written informed consent prior to initiation of any study procedures, including screening procedures (if unable to sign for self, where applicable, legal representative may do so)
6. Subject has not previously been treated for aneurysm or subarachnoid haemorrhage

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Subject is female and pregnant, or breastfeeding
2. Subject has a known allergy to cyanoacrylates
3. Subject has a significant bleeding disorder
4. Subject has known hypersensitivity to any component of the study device or procedural materials
5. Subject is concurrently involved in another investigational study
6. Subject has received any investigational product within 30 days prior to entry into this trial
7. Subject has an acute life-threatening illness other than the neurological disease to be treated in this trial
8. Inability to obtain valid informed consent (consent may be given by legal representative, where applicable)
9. Subject has a life expectancy of less than 1 year due to other illness or condition (in addition to aneurysm)
10. The subject requires treatment for fusiform or lateral aneurysm

Date of first enrolment
01/09/2009

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
United Kingdom

Scotland

Germany

Hungary

Study participating centre
Southern General Hospital
Glasgow
United Kingdom
G51 4TF

Sponsor information

Organisation
Valor Medical Inc. (USA)

Funder(s)

Funder type
Industry

Funder Name
Valor Medical Inc. (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No