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Aneurysm Embolization System (AES) for treatment of intracranial aneurysms

Submission date	Recruitment status	[X] Prospectively registered
09/06/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2020	Circulatory System	

Plain English summary of protocol

Background and study aims
An intracranial aneurysm is a bulge in a blood vessel inside the brain, caused by a weakness in the vessel wall. There are three main treatment options available: observation/medical management, endovascular treatment, and surgical treatment. Although many aneurysms are treated surgically, an increasing number are treated by an endovascular approach, due to the invasive nature of the surgery and its increased risk of complications. In endovascular procedures, a catheter (small tube) is guided through the blood vessels to the location of the aneurysm and soft platinum coils are deployed into the aneurysm to trigger the formation of a blood clot, sealing off the aneurysm. However, the effectiveness of coiling is not as high as surgical clipping (where the aneurysm is sealed shut using a tiny metal clip), as there is an increased need to repeat the treatment. Despite this, endovascular treatment has been proven to improve patient outcomes. The LUNA™ AES provides an alternative to coiling, with the benefits of endovascular treatment but with improved wound healing at the aneurysm and thus a more durable blockage of the aneurysm. The aim of this study is to assess the safety, performance and effectiveness of the LUNA™ AES for the treatment of intracranial aneurysms.

Who can participate?
Patients aged 18 to 75 with an intracranial aneurysm

What does the study involve?
The LUNA™ AES is a small device that is delivered into the aneurysm through a small delivery tube. The device fills the aneurysm with the goal to reduce the risk of the aneurysm bursting and /or bleeding in the future while still maintaining good blood flow to the other blood vessels in the brain. The participant is monitored at various times during the study follow up (up to 36 months). A variety of tests are performed including one or more of the following: physical examination (including medical history), neurological (brain) tests, angiogram (a type of x-ray used to examine blood vessels).

What are the possible benefits and risks of participating?
Potential complications include but are not limited to the following: pain, infection, bleeding, adverse tissue reaction, blood vessel damage, stroke, aneurysm recurrence, unintended movement of the implant, unintended blood clot, and death

Where is the study run from?
Hopital de la Fondation Rothschild (France)

When is the study starting and how long is it expected to run for?
June 2011 to December 2016

Who is funding the study?
Covidien LP (USA)

Who is the main contact?
Dr Michel Piotin

Contact information

Type(s)
Scientific

Contact name
Dr Michel Piotin

Contact details
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Additional identifiers

Protocol serial number
PMCF AES001

Study information

Scientific Title
Aneurysm Embolization System (AES) for treatment of intracranial aneurysms: a post-market clinical follow-up

Acronym
AES

Study objectives
The primary objectives of this study are to characterize the safety, performance and efficacy of the LUNA™ AES for the treatment of intracranial aneurysms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee to Protect People Ile de France XI (Comité de Protection des Personnes Ile de France XI), 03/05/2011

Study design
Prospective multi-centre non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Intracranial aneurysms

Interventions
Current interventions as of 24/04/2014:
The LUNA™ AES is a small device that is delivered into the aneurysm through a small delivery tube. The device fills the aneurysm with the goal to reduce the risk of the aneurysm bursting and /or bleeding in the future while still maintaining good blood flow to the other blood vessels in the brain. The procedure is similar to an angiogram. Using a guiding catheter and imaging, the LUNA™ AES device is placed into the appropriate location. At baseline and following the procedure, the participant is monitored at various times during the study follow up (up to 36 months). A variation of tests are performed and include one or more of the following: medical history collected, physical exam, pregnancy test (if applicable), neurological tests, angiogram and a modified rankin scale.

Previous interventions:
The LUNA™ AES is a small device that is delivered into the aneurysm through a small delivery tube. The device fills the aneurysm with the goal to reduce the risk of the aneurysm bursting and /or bleeding in the future while still maintaining good blood flow to the other blood vessels in the brain. The procedure is similar to an angiogram. Using a guiding catheter and imaging, the LUNA™ AES device is placed into the appropriate location. At baseline and following the procedure, the participant is monitored at various times during the study follow up (up to 12 months). A variation of tests are performed and include one or more of the following: medical history collected, physical exam, pregnancy test (if applicable), neurological tests, angiogram and a modified Rankin scale.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Safety variables look at occurrence and frequency of:
1. Adverse Events (AEs)
2. Adverse Device Effects (ADEs)
3. Serious Adverse Events (SAEs)
4. Unanticipated Adverse Device Effects (UADEs)

Efficacy variables relate to the ability of the device to embolize the aneurysm at select time points

Key secondary outcome(s))
Performance variable evaluate the systems use in helping to get the device to aneurysm

Completion date
01/12/2016

Eligibility

Key inclusion criteria
1. Sex: male or female
2. Age: 18 to 75 years
3. Subject must be able to understand and be willing to sign an consent form
4. Subject must be considered a candidate for aneurysm coiling
5. Subject must be willing and able to participate in all aspects of the study and agree to comply with all study requirements for the duration of the study. This includes availability of reliable transportation and sufficient time to attend all follow-up visits
6. Subject is diagnosed with an intracranial aneurysm that has never been previously treated
7. The location, shape, neck size, overall aneurysm geometry and size must be consistent with the parameters set forth in the Instructions for Use (IFU) for the LUNA™ AES in order to be acceptable for treatment
8. Subject must be of sufficient and stable medical health, as evaluated by the Prinicipal Investigator (PI)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
63

Key exclusion criteria
1. Subject has a fusiform aneurysm
2. The target aneurysm has been previously treated by surgical or endovascular means
3. Subject has symptomatic congestive heart failure, cardiac arrhythmia or unstable coronary artery disease
4. Subject has pre-existing respiratory disease such as chronic obstructive pulmonary disease (COPD), pneumonia or cancer
5. Subject has renal and/or hepatic insufficiency
6. Subject has systemic infection in the body at the time of the LUNA™ AES procedure

7. Subject has history of neurovascular or neurologic disease that in the opinion of the Investigator would make them a poor candidate for the LUNA™ AES procedure
8. Subject is contraindicated for radiographic contrast media
9. Subject has severe coagulopathy (prothrombin time > 3 seconds over control or platelet count < 100,000) or is presently taking heparin, Coumadin® (warfarin), or other anticoagulants or other medications which impede coagulation or platelet aggregation
10. Subject has collagen vascular disease
11. Subject is undergoing chronic steroid therapy
12. Subject is undergoing immunosuppressive therapy
13. Subject has relative contraindication to angiography (e.g., serum creatinine level > 2.5 mg/dL)
14. Female subject who is pregnant (i.e., has a positive urine or blood pregnancy test prior to device implant), is suspected to be pregnant, is lactating or is of childbearing potential but refuses to use adequate contraception during the study
15. Subjects who have poorly controlled psychiatric disease including but not limited to manic-depressive disorder, schizophrenia, borderline personality disorder, depression or suicidal tendencies
16. Subject currently uses or has a history of illicit drug(s) or abuses alcohol (defined as regular or daily consumption of more than 4 alcoholic drinks per day)
17. Subject has participated in a clinical study with an investigational new drug, biological, or therapeutic device within 28 days prior to enrollment in this study, and does not agree to abstain from participation in other clinical trials of any kind during this study
18. The subject is unable to comply with trial procedures or protocol
19. Any co-morbid disease or condition expected to compromise survival or ability to complete follow-up assessments to 6 months

Date of first enrolment
14/06/2011

Date of final enrolment
24/04/2014

Locations

Countries of recruitment
Belgium

France

Germany

Italy

Poland

Sweden

Study participating centre
Hopital de la Fondation Rothschild
Paris

France
CEDEX 19

Sponsor information

Organisation
Covidien LP (USA)

ROR
https://ror.org/00grd1h17

Funder(s)

Funder type
Industry

Funder Name
Covidien LP (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?
Results article	results	01/12/2018	17/08/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes