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Altura post-market registry study: Altitude

Submission date 07/02/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/03/2017	**Overall study status** Completed	
Last Edited 21/07/2020	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
An aortic aneurysm is a swelling of the aorta which is the major artery (blood vessel) in the abdomen (tummy). If left untreated, the aneurysm can get bigger and bigger until it bursts or tears which can be a life-threatening event. In order to try to prevent this happening, surgery may be necessary. Aneurysms are often treated with endovascular stent grafts, a type of minimally invasive keyhole surgery which involves inserting a stent (small mesh tube) to support the aorta and prevent it from rupturing. This procedure is called EVAR (endovascular aortic repair) and there are several different types of stents available, as this surgery is advancing with improvements in technology. New types of stents have to undergo testing to check that they are safe and work as they should do. The purpose of this study is to gather information about the use of the Altura stent graft. The study aims to gather long term data on patients who are treated with the Altura™ stent graft in a real world situation.

Who can participate?
Adults with an Altura stent graft who are 60 years old and over.

What does the study involve?
Participants who have a planned surgical treatment with the Altura stent graft system consent to participate in this study. This study does not change their standard care plan. Before surgery, data is collected about the participants outlining their basic details and their medical history in regards to their aortic aneurysm. Participants then undergo the surgical procedure and have the Altura stent placed in the aneurysm as done to the standard level of care. Participants are followed up regularly to see how successful the stent is at preventing rupture 30 days after the procedure and then yearly for five years.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
Cambridge University Hospitals (UK)

When is the study starting and how long is it expected to run for?
November 2016 to September 2024

Who is funding the study?
Lombard Medical (UK)

Who is the main contact?
Dr Natalie Hayes, natalie.hayes@lombardmedical.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2017-000604-24

Protocol serial number
ALT_001

Study information

Scientific Title
Multi-centre observational post-market real world registry

Study objectives
The aim of this study is to evaluate the efficacy of the Altura stent graft system, in real world settings, both in the short and long term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design

Multi-centre, observational longitudinal study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Abdominal aortic aneurysms

Interventions
Participants are identified as eligible for the study by their clinical team if they have planned for treatment with the Altura stent graft system. Patients are provided with a patient information sheet detailing the ALTITUDE registry and asked to consent to participating. Once consent has been obtained then baseline, anonymous data about patient demographics and anatomical details relating to their aortic aneurysm is recorded onto the online case report form (eCRF). Their treatment pathway is not altered in any way by participating in the study.

Participants then undergo the surgical procedure which places the Altura stent graft on the aneurysm. This is done to the normal standard of care. Further operative details are recorded at this time in regards to how the surgery went.

Participants are regularly followed up in order to measure how well the ALtura stent graft is working. The registry aims to collect data at very standard time follow up time points for the patients, as are usually used for standard of care. Data is recorded onto the eCRF about the patient's condition at four weeks, six and 12 months and then annually for five years from treatment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Procedural technical success is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days
2. Freedom from endoleak of any type, apart from type 2 over 5 years is measured using the the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 1, 2, 3, 4 and 5 years
3. Assessment Peri-operative Safety Parameters is measured using the the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days post-procedure

Key secondary outcome(s))
1. Freedom from conversion to open surgical repair through to five years is measured using the patient notes at 30 days and then annually to 5 years
2. Freedom from aneurysm rupture is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
3. Clinically significant migration, requiring intervention or an increased frequency of surveillance through to five years is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days,

and 1, 2, 3, 4, and 5 years
4. Aneurysm enlargement (>5mm) through to five years is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
5. Aneurysm regression (>5mm) through to five years is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
6. Secondary endovascular procedures of any type through to five years is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
7. Secondary vascular and/or endovascular procedures for resolution of:
7.1. Endoleak of any type is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
7.2. Device occlusion (due to thrombus or other causes) is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
7.3. Device migration leading to abdominal aortic aneurysm sac expansion (>5mm diameter increase) is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
7.4. Device defect is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
7.5. Device Patency and Integrity throughout the study is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years
7.6. Incidence of distal thrombosis, embolization and iliac stenosis is measured using the patient notes and imaging records (either CT scan, or ultrasound +/- abdominal x-ray, as determined by the investigator) at 30 days, and 1, 2, 3, 4, and 5 years

Procedural and in-hospital evaluations:
1. Total intervention time (skin-skin) is measured using patient notes at discharge
2. Total theatre use time (including anaesthesia) is measured using patient notes at discharge
3. Fluoroscopy time is measured using patient notes at discharge
4. Contrast volume used is measured using patient notes at discharge
5. Estimated blood loss is measured using patient notes at discharge
6. Incidence of transfusion is measured using patient notes at discharge
7. Time in ICU is measured using patient notes at discharge
8. Time to hospital discharge is measured using patient notes at discharge
9. Proportion of patients where a decision is made by the surgical team that the patient is fit to be discharged from the hospital <24h post procedure is measured using patient notes at discharge
10. Readmissions for access site complications is measured using patient notes at 30 days, and 1, 2, 3, 4, and 5 years
11. Readmissions for other complications is measured using patient notes at 30 days, and 1, 2, 3, 4, and 5 years

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Patient being implanted with an Altura stent graft
2. Male or female at least 60 years' old
3. Subject has signed informed consent for data and image release
4. Subjects with abdominal aortic aneurysm and eligible for endovascular repair

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Currently participating in another related study where primary endpoint has not been reached yet
2. Mycotic or infected aneurysms
3. Aneurysms associated with a known connective tissue disorder
4. Occluded iliac access vessels
5. Ruptured abdominal aortic aneurysm
6. Patients deemed by the investigator to lie outside the Instructions for Use of the Altura®-System
7. Life expectancy less than 2 years
8. Known allergy to any of the device components
9. Pregnancy or breastfeeding or any plan to become pregnant during the study

Date of first enrolment
31/03/2017

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Cambridge University Hospitals Trust
Hills Road

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CB2 0QQ

Sponsor information

Organisation
Lombard Medical

ROR
https://ror.org/00447xj53

Funder(s)

Funder type
Industry

Funder Name
Lombard Medical

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available as the dataset is of commercial importance and therefore will not be made freely available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes