

Comparison of EVAR and ESAR for Infrarenal Aortic Aneurysms With a Wide Proximal Neck

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Age 18 years or older * Provided written informed consent * Clinical necessity for treatment of the AAA, according to the current guidelines in the geographies participating * Elective repair * Eligible anatomy for treatment with the Endurant II/IIIs stent graft system and Heli-FX EndoAnchor system according to the IFU of both devices * Infrarenal neck diameter ≥ 28 mm and ≤ 32 mm * Proximal neck length ≥ 10 mm

Exclusion Criteria:

* Anatomy outside the IFU of the Endurant II/IIIs stent graft system and Heli-FX EndoAnchor system * Planned use of AUI main body device * Patient is participating in another clinical study, potentially conflicting with the outcomes of the current study. * Patient with eGFR < 30 ml/min/1.73m² before the intervention * Patient's life expectancy < 2 years as judged by the investigator * Patient has a psychiatric or other condition that may interfere with the study * Patient has a known allergy to any device component * Patients with a systemic infection who may be at increased risk of endovascular graft infection. * Patient has a coagulopathy or uncontrolled bleeding disorder * Patient has a ruptured, leaking, or mycotic aneurysm * Patient is not eligible for standard EVAR * Patient had a Cerebro Vascular Accident (CVA) or a myocardial infarction (MI) within the prior three months * Patient is pregnant (Female patients of childbearing potential only) * Patient has active COVID-19 infection or has been diagnosed with long COVID-19 requiring hospitalization within the 6 months prior to procedure. * Patient has previously been treated with stent grafts in the aorto-iliac arteries

Conditions & Interventions

Interventions:

DEVICE: endovascular aneurysm repair (EVAR) using the Endurant II/IIIs stent graft system, DEVICE: endosuture aneurysm repair (ESAR) using Heli-FX EndoAnchor system

Conditions:

Aortic Aneurysm, Abdominal

Keywords:

AAA, Endovascular treatment, Wide proximal neck, EndoAnchors, Infrarenal, EVAR (Endovascular aneurysm repair), ESAR (Endosuture aneurysm repair), Endurant II/IIIs stent graft system, Heli-FX EndoAnchor system

More Information

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Principal Investigator:

Phase: NA

IRB

Number:

System ID: NCT05484115

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