Medtronic

HERCULES Trial

An investigator-driven randomized controlled trial designed to prospectively compare endosuture aneurysm repair (ESAR) to standard endovascular aneurysm repair (EVAR) clinical outcomes in treatment of infrarenal abdominal aortic aneurysm (AAA) in subjects having wide proximal aortic neck diameters (≥ 28 mm and ≤ 32 mm) and meeting device IFU requirements.

You're commited.
So are we.

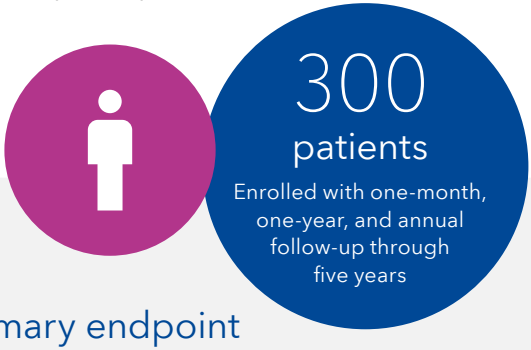
Strength in evidence

HERCULES is designed to collect clinical evidence to better understand the role of ESAR with the Heli-FX™ EndoAnchor™ system in the treatment of challenging wide neck AAA patients.

HERCULES design

HERCULES is a post-market, prospective, global, multicenter, randomized (1:1), two-arm, superiority trial designed to compare ESAR to standard EVAR clinical outcomes in treatment of infrarenal AAA in patients having wide proximal aortic neck diameters (≥ 28 mm and ≤ 32 mm).

All imaging-based endpoints will be based on computed tomography angiography (CTA) and analyzed by a core lab. Imaging will be collected for all follow-up time points.



Primary endpoint

Composite of core lab reported data from CT with contrast of freedom from:

1. Type Ia endoleak, and
2. Migration of the proximal portion of the stent graft ≥ 5 mm *(compared to one-month imaging),* and
3. Aneurysm sac growth ≥ 5 mm *(compared to one-month imaging).*

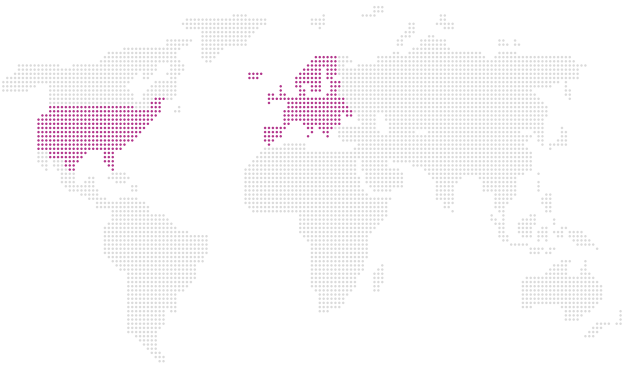
Secondary endpoints

Evaluated using core lab reported data.
Freedom from:

- Type Ia endoleak
- Migration of the proximal portion of the stent graft ≥ 5 mm *(compared to one-month imaging)*
- Aneurysm growth ≥ 5 mm *(compared to one-month imaging)*
- Neck dilatation ≥ 3 mm

Up to 40 centers

United States and Europe



Selected safety and performance ancillary objectives

- Adequate EndoAnchor penetration (core lab assessed)
- Device-related AEs/SAEs
- Procedure-related AEs through 30 days
- All endoleaks at all timepoints (core lab and site assessed)
- Aneurysm sac changes over time
- Clinically significant migration over time
- Migration ≥ 5 mm and ≥ 10 mm
- Freedom from proximal ring expansion
- Composite of freedom from migration ≥ 5 mm, type 1a endoleak, sac growth ≥ 5 mm or neck dilatation ≥ 3 mm at all timepoints

HERCULES rationale

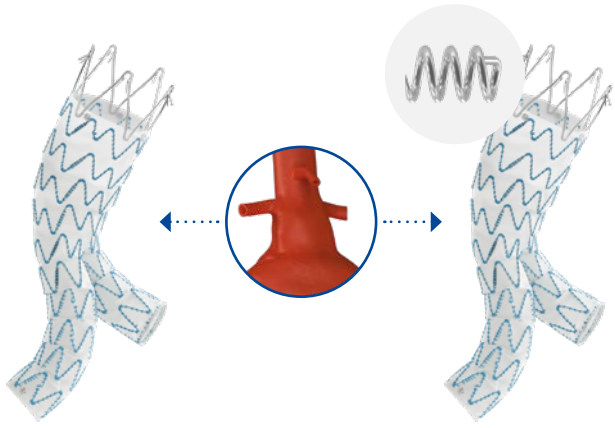
- EVAR has been established as a safe and effective repair for AAA. However, recent published literature shows wide infrarenal aortic necks are at greater risk for loss of proximal seal and related events.[1-4]

- Recent ANCHOR data shows promising results in treating hostile necks including wide neck anatomy.[5] Higher level evidence will help to further guide treatment algorithms.

- **This trial will provide a foundation to further characterize the clinical outcomes of treatment for patients with infrarenal AAA with wide proximal aortic neck diameters.**

EVAR

ESAR



Endurant™ II/IIs stent graft system

Endurant II/IIs stent graft plus Heli-FX EndoAnchor system

References

[1] Kouvelos GN, et al. *J Cardiovasc Surg*. 2019;60:167-174.
[2] Gargiulo M, et al. *J Vasc Surg*. 2017;66:1065-1072.
[3] McFarland, et al. *J Vasc Surg*. 2019;69:385-393.
[4] Laczynski, Caputo. *J Vasc Surg*. 2021;74:309-315.
[5] Prof. Michel Reijnen. Podium First: ESAR is more than reinforced proximal seal: three-year ANCHOR study results on wide necks and video technique edited case. Presented at: Charing Cross International Symposium; April 26, 2022;London, UK.

Brief statement

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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medtronic.eu/aortic

Europe
Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

medtronic.eu

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