Nectero Medical

# Do you have AAA?

If so, you may be eligible for a study of a novel approach to treat your small to medium-sized AAA

Nectero Medical, Inc. is conducting a clinical trial for the Nectero Endovascular Aneurysm Stabilization Treatment (Nectero EAST®) System in small to mid-sized abdominal aortic aneurysms (AAA).

Only a doctor can determine if you are a good candidate for the trial

This guide is to help you further understand the drug, device, procedure and potential for participation in this clinical trial

Participation in this study is strictly voluntary

*Caution: Investigational Device. Limited by US law to investigational use only. Not available for sale.*

## What Is an Abdominal Aortic Aneurysm (AAA)?

The aorta is the largest blood vessel in the body. It carries blood away from the heart to the rest of the body.

The abdominal aorta is the part of the aorta located in the abdomen (Figure 1).

**Figure 1.**
Healthy abdominal aorta

**Figure 2.**
Abdominal aorta with aneurysm
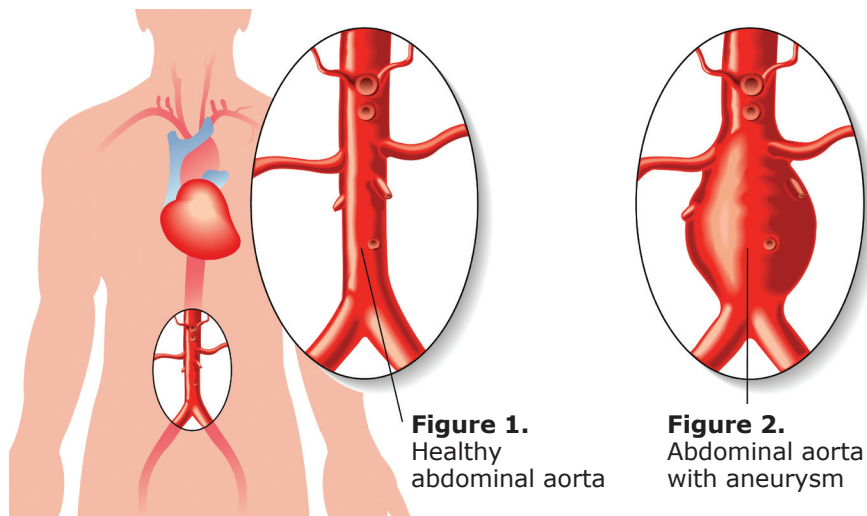
An aneurysm is the bulging or ballooning of a weakened area of a blood vessel.

- The wall of the aorta can become weak due to family history, age, disease or trauma.
- This may cause the aortic wall to bulge, leading to an AAA (Figure 2).
- As the bulge grows, the wall of the aorta becomes weaker.
- This may cause the aorta to rupture and lead to massive internal bleeding requiring immediate medical attention.

## What Are Current Treatments for Small to Mid-sized AAA?

No proven treatment options are currently available for small to mid-sized aneurysms; it is recommended to monitor the growth in size of the AAA over time, known as surveillance or "watching and waiting".

Once AAA reaches a certain size (usually greater than 5.5cm in males or greater than 5.0cm in females) and/or symptoms change, the doctor will assess and discuss open surgical repair or the placement of a large tube (graft) inside the AAA to line the aortic vessel.

## What Is the Nectero EAST® System?

Nectero Medical is developing a novel treatment that may slow growth and potentially prevent rupture/bursting of small to mid-sized AAA.

The Nectero EAST® procedure is performed using sedation. A catheter, a thin, long tube-like device with inflatable balloons at the end, is introduced through a small cut in the groin.

Once in the aneurysm, pentagalloyl glucose or PGG mixture, is delivered via holes in the balloon directly into the aneurysmal wall where it acts to strengthen the wall and potentially prevent further weakening. This is a one-time treatment that is expected to have a lasting effect. The entire procedure takes ~ 1 hour.

**Treatment with the Nectero EAST System may:**

✔ Slow or prevent the aneurysm from growing.

✔ Lower the risk of rupture (bursting).

✔ Delay and maybe prevent the need for major endovascular or open surgical repair.
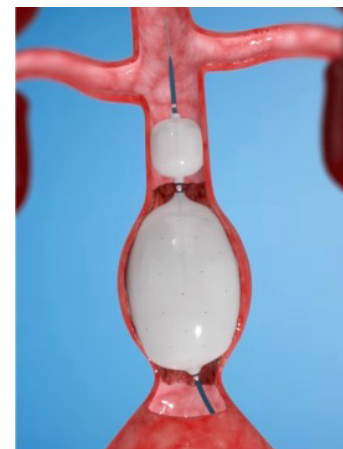
# Who Is a Candidate for the Study?

The study is focused on patients with AAA size 3.5-5.0cm (male) or 3.5-4.5cm (female). If you qualify for the study, you will be randomly assigned (50:50 chance) to either:

1. Receive the study treatment
   - The hospital staff will schedule you for the procedure within 30 days of your recent CT scan.
2. Be in the non-treatment group
   - You will not undergo the study treatment, but will be followed for increased evaluation of your AAA.

All patients may benefit from the additional observation of their aneurysm throughout the study period. Additional information on the condition, procedure, risks and benefits can be provided by your physician.

# What to Discuss With Your Doctor?

- What are the other options for treating AAA?
- What are the risks and benefits of the procedure?
- How often are the follow-ups and which tests will be performed?
- How will the cost of participating in the study be covered?

**Note: It is important for the patient to keep all scheduled imaging tests and appointments during the follow-up period to assess the aneurysm status.**

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