An Investigational Non-randomized Competitive Prospective study of the INCRAFT* Stent Graft System, In subjects with Abdominal Aortic Aneurysms

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The purpose of this clinical study is to evaluate the safety and efficacy of the Cordis AAA Stent Graft System, INCRAFT*, in the treatment of patients with Abdominal Aortic Aneurysm (AAA).

Ethical review	Approved WMO
Status	Will not start
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON38193

Source
ToetsingOnline

Brief title
INCEPTION Study

Condition

- Aneurysms and artery dissections

Synonym
A localized enlargement of the aorta (biggest blood vessel in the body) below the kidneys

Research involving
Human

Sponsors and support

Primary sponsor: Johnson & Johnson

Source(s) of monetary or material Support: Cordis Corporation

Intervention

Keyword: Abdominal Aortic Aneurysms (AAA), customizable, INCRAFT Stent Graft System, low profile stent graft system, three-piece modular system

Outcome measures

Primary outcome

The primary endpoints are defined as follows:

1. Efficacy: successful aneurysm repair (absence of type I or III endoleak)

within 30 days post-procedure as confirmed by contrast CT-scan.

2. Safety: the absence of major adverse events (death, MI, CVA and renal

failure) within 30 days post-procedure.

Secondary outcome

Secondary endpoints are defined as follows:

1. Absence of aneurysm enlargement - defined as an increase in maximum aortic

diameter/circumference/cross sectional area of more than 10% or in total

aneurysm volume of more than 5% at 1 year, 3 years, and 5 years post-procedure

compared to the baseline CT assessment performed within 30 days by quantitative

AAA measurements.

2. Absence of stent-graft migration assessed at 1 year, 3 years, and 5 years

post-procedure compared to the baseline evaluation within 30 days

post-procedure.

3. Absence of stent-graft fractures assessed within 30 days, 6 months, and

annually through 5 years post-procedure.

4. Absence of endoleak (types I or III) at 1 year, 3 years, and 5 years

post-procedure.

5. Absence of endoleak type IV.

6. Absence of deployment-related complications within 30 days, 6 months, and annually through 5 years post-procedure.

7. Absence of device-related complications within 30 days, 6 months, and annually through 5 years post-procedure.

8. Absence of systemic complications within 30 days, 6 months, and annually through 5 years post-procedure.

9. Pain post-operatively compared to external comparator, as measured by the SF36v2 at screening, 30 days, 6 months, 1 year follow up.

10. Physical functioning post-operatively compared to external comparator, as measured by the SF36v2 at screening, 30 days, 6 months, 1 year follow up.

11. Procedure-related clinical utility measures evaluated through subgroup analyses.

Study description

Background summary

It is estimated that Abdominal Aortic Aneurysms (AAA) occur in 27 million people worldwide. Left untreated they are likely to rupture, with 80 to 90 percent of all ruptured aneurysms resulting in death. These deaths can be avoided if an aneurysm is detected and treated before it ruptures.

The oldest therapy to prevent rupture of AAA is open surgical repair of the aneurysm, which has been the standard treatment for many years. Surgery of AAA requires general anaesthesia, a 20-30 cm incision (=cut) and major surgery of your abdomen. This surgery has many risks and many AAA patients cannot even undergo the procedure due to these risks.

Catheter-based endovascular technology is a recent option (since 1991) to

surgery and is part of *minimally invasive* procedures to treat AAA and prevent rupture with the potential to reduce operative risks (such as bleeding) and shorten hospital stays. An example of such technology is the Cordis Abdominal Aortic Stent Graft System, named INCRAFTTM, which is examined in this clinical study.

Clinical results with endovascular aneurysm repair (EVAR) have shown lower mortality and morbidity rates initially when compared to open surgery. It is less invasive than open repair and has also extended treatment options to patients who cannot undergo conventional surgical procedures due to a high operative risk. As EVAR technology evolves, it allows treatment of AAA with increasing complexity of the aortic neck and access vessels.

In the last five years, there have been over 20,000 endovascular stent graft devices implanted in patients with aortic aneurismal disease, with generally favorable results. There are currently a variety of devices approved for EVAR, but even with the technological enhancements there is still room for improvement. Patients with small, tortuous, calcified access vessels account for 6 to 19 percent of procedures and are at higher risk for access related complications such as iliac rupture, dissection and pseudoaneurysm. In addition, device placement accuracy can be challenging, resulting in unintentional renal or iliac coverage or the need for acute proximal or distal extension utilization.

The Cordis INCRAFT* is a new customizable, low profile stent graft system. The INCRAFT* device consists of a three-piece modular system: the aortic bifurcate (with supra-renal fixation barbs) and two iliac limb prostheses. Each prosthesis is constructed of a seamless, low porosity, woven polyester graft supported by a series of short, electropolished, laser-cut nitinol stent-rings throughout the entire length. It features bilateral in-situ length adjustment up to 3cm, partial proximal re-positioning and a *fewfits most* surgical graft concept for customization. The integrated delivery system has a 13 Fr inner diameter and 14 Fr outer diameter.

One advantage of the INCRAFT* AAA Stent Graft System is that it is designed for endovascular repair of infrarenal AAAs even for patients with smaller access arteries. Furthermore, INCRAFT* is a stent-graft system with delivery mechanism, which may assist the investigator to deploy the device in a controlled, consistent, and precise manner within the aortic neck and iliac/access arteries. In addition to the stents being visible under fluoroscopy, radiopaque markers are sewn onto each component to aid visualization and to facilitate accurate placement. To optimize limb placement, INCRAFT**s design enables the investigator to perform unique in-situ sizing for optimal deployment specific to each subject*s independent anatomy.

Initial experience with the device in the INNOVATION multicenter study is promising and further clinical data would reinforce the knowledge on safety and

efficacy of this AAA stent graft.

Study objective

The purpose of this clinical study is to evaluate the safety and efficacy of the Cordis AAA Stent Graft System, INCRAFT*, in the treatment of patients with Abdominal Aortic Aneurysm (AAA).

Study design

A Multi-center prospective, open label, non-randomized study to evaluate the safety and efficacy of the Cordis AAA Stent Graft System, INCRAFT*, in the treatment of patients with infrarenal Abdominal Aortic Aneurysm (AAA).

Intervention

Endovascular Aneurysm Repair (EVAR).

Study burden and risks

It is important to know that the below risks are known complications of stent graft implantation procedures and are not specific to this study.

Possible side effects include but are not limited to: amputation; anesthesia complications; enlargement of the aneurysm; aneurysm sac rupture; damage to the aorta (largest artery in your body); formation of a blood clot in one of your arteries or veins; bleeding complications or bleeding disorder; hematoma (bruising at access site); gastrointestinal complications; abnormal heart rhythm; cardiac complications; cardiac failure (inability to supply sufficient blood to the body) or heart attack; stroke; claudicatio (pain in legs during walking); conversion to open surgery; death; edema (fluid accumulation body tissue); endoleak (persistent blood flow outside the stent graft); fever; pseudoaneurysm (collection of blood in surrounding tissue resulting from a leaking hole in an artery); complications in the reproductive organs and urinary system; infection; impotence; lymphatic complications; paraplegia or paraparesis (injured motor or sensory function in the lower limbs);post-implant syndrome (general reaction of the body against an implanted device, which can lead to flu-like feelings, headache, backache); complications in the lungs; renal complications; complications at the access sites; wound complications; injury or narrowing of an artery or vein; neurological complications.

Possible risks associated with the devices include but are not limited to: migration of the stent graft, complication with the placement of the stent graft, wear or erosion of the graft material, fracture of the stent and graft leakage.

There may be unforeseeable risks to you that are not known at this time. Some of these complications may require urgent surgery. You should be aware that the success of the procedure cannot be guaranteed, and if not successful, repeat intervention(s) may be necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Male or Female * 18 years of age.
2. Proximal aortic neck is 17-31mm in diameter.
3. Supra-renal aorta at 20mm above the intended landing location is smaller than the nominal diameter of the aortic bifurcate prosthesis to be used.
4. Infra-renal aortic neck is: * 10mm in length with supra-renal and infra-renal neck angulations * 60°.

5. Subject has at least one of the following:
a. AAA size > 5.0 cm
b. Increase of the AAA diameter of >0.5 cm over the last 6 months
6. Abdominal treatment length (lowest renal artery origin to the aortic bifurcation) of * 9.4cm.
7. Aortic bifurcation > 18mm in diameter.
8. Iliac landing zone * 15mm in length.
9. Iliac landing zone 7-22mm in diameter.
10. Minimum access vessel size of * 5mm.
11. Minimum overall AAA treatment length (from lowest renal artery to distal landing zone) of 128mm.
12. Understands study requirements and treatment procedures, signs the informed consent form prior to any study procedure, and is willing to comply with all specified follow-up evaluations.

Exclusion criteria

1. Vascular anatomy in which the placement of the stent-graft will cause occlusion of both internal iliac arteries or necessitates surgical occlusion of both internal iliac arteries.
2. Subject has one of the following :
a. Aneurysm sac rupture or leaking abdominal aortic aneurysm;
b. Mycotic, dissecting, or inflammatory abdominal aortic aneurysm;
c. Clinically significant acute vascular injury due to trauma.
3. Significant aortic or iliac mural thrombus, calcification, or plaque that would compromise fixation and seal of the device.
4. A reversed conical aortic neck defined as > 3mm distal increase over a 10mm length in the planned seal zone.
5. Thoracic aortic aneurysm * 45mm.
6. Any aortic dissection.
7. Morbid obesity (BMI of > 40.0kg/m2) or other clinical conditions that limit required imaging studies or visualization of the aorta.
8. Renal insufficiency (Creatinine > 2.0mg/dL (= 177µmol/L)) or on renal dialysis.
9. Known allergy or intolerance to nickel titanium (nitinol), Polyethylene terephthalate (PET), polytetrafluoroethylene (PTFE).
10. Known contraindication to undergoing angiography or anticoagulation (e.g. contrast allergies which cannot be treated).
11. Connective tissue disorder (such as Marfan's Syndrome or Ehler's-Danlos Syndrome).
12. Coagulopathy, bleeding disorder, or other hypercoagulable state.
13. Organ transplant recipient or subject requiring systemic immunosuppressant therapy.
14. Cerebral Vascular Accident (CVA), MI or intracranial bleeding within 3 months prior to the procedure.
15. Active infection or chronic systemic illness at the time of the index procedure that may interfere with the study objectives.
16. Major surgical procedure within 1 month prior to index procedure or pre-planned within 1 month afterwards.
17. Co-existing condition with a life expectancy of less than 2 years at time of procedure.

18. Current or planned participation in any another investigational drug or medical device clinical study that has not completed primary endpoint(s) evaluation.
19. Existing AAA surgical graft and/or a AAA stent-graft system.
20. Women of child bearing potential whom are pregnant, lactating, or planning to become pregnant during the course of the trial.
21. Other medical, social, or psychological issues that in the opinion of the investigator preclude them from receiving this treatment, and the procedures and evaluations pre- and post-treatment.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	14
Type:	Anticipated

Medical products/devices used

Generic name:	INCRAFT Stent Graft System
Registration:	No

Ethics review

Approved WMO Date:	11-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2012

Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL37217.029.11