CratosTM Thoracic Branch Stent Graft System is used for the treatment of aortic lesions including aortic dissection, Intramural Hematoma and Penetrating Atherosclerotic Ulcer.

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To evaluate efficacy and safety of Cratos* Branch Stent Graft System in treatment of lesions (dissection, IMH and PAU) in descending aorta.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON56955

Source
ToetsingOnline

Brief title
CRATOS

Condition

- Aneurysms and artery dissections

Synonym
Acute Complicated Type B Aortic Dissection

Research involving
Human

Sponsors and support

Primary sponsor: Shanghai MicroPort Endovascular MedTech (Group) Co., Ltd.
Source(s) of monetary or material Support: The sponsor: Shanghai MicroPort Endovascular MedTech (Group)

Intervention

Keyword: Acute Complicated Type B Aortic Dissection, EVAR, TBAD, TEVAR

Outcome measures

Primary outcome

30-day all-cause Mortality rate (Cohort 1: Acute Complicated Type B Aortic

Dissection)

Secondary outcome

Composite of the following events from the time of enrolment through 12-month

(Cohort 1: Acute Complicated Type B Aortic Dissection):

• Device Technical Success

• Absence of:

- Aortic rupture

- Lesion-related mortality

- Disabling Stroke

- Permanent paraplegia

- Permanent paraparesis

- New onset renal failure requiring permanent dialysis

- Additional unanticipated post-procedural surgical or interventional procedure

related to the device, procedure, or withdrawal of the device system.

• Ongoing Primary Clinical Success

Defined as device technical success, with absence of the following events from the initiation of the index endovascular procedure and at all appropriate follow-up windows:

• Aortic rupture

• Type I or III endoleak

• Infection or aortic thrombosis

• Extension of dissection (Proximally or Distally)

• New dissection

• Aortic enlargement in the region encompassed by the Index Lesion

• False lumen perfusion through the primary entry tear

• Lesion-related mortality

• Loss of device integrity

• Loss of aortic or aortic branch patency

• Migration

• Disabling stroke within 30 days of the index endovascular procedure only

Paraplegia within 30 days of the index endovascular procedure only

• Paraparesis within 30 days of the index endovascular procedure only

• New onset of renal failure requiring dialysis within 30 days of index procedure or additional unplanned secondary intervention

• New ischemia

• Additional unanticipated surgical (including conversion to open surgery) or interventional (placement of additional unanticipated endovascular devices) procedure related to the device, procedure, or withdrawal of the delivery system.

• Type II or IV endoleak

• Aortic dissection false lumen thrombosis status

• Change of maximum aortic dissection diameter, false lumen, and true lumen

diameter

• False Lumen perfusion through a non-aortic arch branch vessel

Study description

Background summary

Aortic dissection is defined as disruption of the medial layer provoked by intramural bleeding, resulting in separation of the aortic wall layers and subsequent formation of a True Lumen and a False Lumen with or without communications. In most cases, an intimal tear is the initiating condition, resulting in tracking of the blood in a dissection plane within the media. This process is followed either by an aortic rupture in the case of adventitial disruption or by a re-entering into the aortic lumen through a second intimal tear.
Acute aortic dissection is the most catastrophic aortic event. The disease will lead to high mortality and morbidity without appropriate and time-sensitive treatment. Incidence of aortic dissection ranges from 3 to 10 cases per 100,000 patients, while in Sweden, this number can be as high as 16 cases per 100,000 patients ((Howard et al., 2013; McClure et al., 2018; Olsson et al., 2006). The true prevalence of aortic dissection maybe underrepresented since many patients die before reaching the hospital, with the cause of death never proven.
Most important risk factors for aortic dissection are increased blood pressure and this result in greater stress against the aortic wall, other risk factors including gender (male), age (60s and 70s), atherosclerosis, smoking, pre-existing aneurysm, aortic valve defects and previous surgery on the aorta. Genetic disorder such as Marfan*s syndrome, may also predispose the aorta to dissect. Traumatic chest injury may also cause dissection.

Current treatment approaches for descending thoracic aortic pathologies are thoracic endovascular aortic repair (TEVAR), best medical treatment (BMT) or Optimal medical therapy (OMT) and open surgical repair (OSR). Benefits and risks of each treatment strategy were different. TEVAR was widely used for TBAD patients in the last decade due to the lower mortality and morbidity compared with OSR.

Study objective

To evaluate efficacy and safety of Cratos* Branch Stent Graft System in treatment of lesions (dissection, IMH and PAU) in descending aorta.

Study design

Prospective, interventional, multicentre, single-arm performance objective study

Intervention

Endovascular repair of the descending thoracic artery may include the following:
• General, regional, or local anaesthesia administration before the index procedure.
Antibiotic administration, according to standard practice
• Systemic heparin administration, according to standard practice
• Spinal cord ischemia prevention techniques, according to standard practice
• Stent-graft introduction into the access site
• Angiographic verification of aorta, LSA and adjacent artery characteristics performed at the time of the procedure and before Graft-stent introduction.
• Fluoroscopic guidance used for stent graft placement throughout the endovascular procedure.
• Stent graft introduction and deployment
• If deemed necessary by the investigator, aortic extender can be implanted at the distal end of the stent graft in the aorta and/or the branch vessel. At least 3 cm overlap is required for distal aortic implantation, and 2cm overlap for distal branch vessel implantation.
• At the discretion of the investigator, adjunct radiologic modalities may be used to assess the vasculature and to optimize prosthesis implantation.
• Delivery system withdrawal
• Angiography at the completion of the endovascular procedure to document the status of the graft-stent and surrounding aorta and vasculature.
Detailed information of CratosTM Branch Stent-Graft system implantation can be found in the Microport Endovascular CratosTM Thoracic Branch Stent Graft System IFU.
Procedural measures will be required to be recorded in the electronic Case Report Forms (eCRF), Specifically, the following information:
• The CratosTM Device and ancillary accessory devices information.
• Device malfunction or device deficiencies
• Additional procedure/-s performed during the TEVAR, and information on any additional devices that has been implanted during the procedure.
• Procedural medication.
• Procedure time and anaesthesia time.
• Fluoroscopy time and dose and contrast volume
• Any adverse events, endpoint events, procedure complications,
• Protocol deviations.
• Device serial and/or LOT number

Study burden and risks

Potential Risks
Complications associated with the use of CratosTM Device in this indication may include the following:
Clinically related complications
• Skin disorder
• Admission infection
• Incision hematoma
• Fever or prolonged fever
• Difficulty in breathing
• Haemorrhage
• Injury to iliac artery, femoral artery, or other blood vessel
• Heart disease
• Lymphatic leakage
• Arteriovenous fistula
• Renal obstruction
• Stent thrombosis
• Distal limb vascular embolism
• Graft infection
• Aneurysm rupture
• Paralysis or paraplegia
• Death
Device related complications
• Endoleak
• Stent graft migration, seal failure
• Side branch opening deviates from branch vessels and affects branch blood flow.

Potential Benefits
Benefit of treatment with CratosTM Stent-graft system in patients with type B aortic dissection and/or IMH and /or PAU has not been documented.
Like already marked TEVAR devices, CratosTM Thoracic Stent-Graft system may provide endovascular repair of descending thoracic artery lesions, and therefore reducing all-cause mortality. Relative to endovascular repair of DTA lesions using a non-branched endoprosthesis, repair with CratosTM Thoracic Branch Stent-Graft System may offer the following benefits:
• Avoidance of complications associated with LSA coverage, including:
- Arm weakness and / or claudication
- Stroke
- Spinal cord ischemia

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

Presence of thoracic aortic pathology (Dissection, including IMH and ULP; and PAU) deemed to warrant surgical repair which requires proximal graft placement in Zone 2
2. Age >=18 years at time of informed consent signature
3. Informed Consent Form (ICF) is signed by Subject or legal representative
4. Must have appropriate proximal aortic landing zone, defined as:
• Landing zone inner diameters between 23-41 mm
• The length of landing zone >=15mm
• Landing without heavily calcified or heavily thrombosed
• Dissection Patients: Primary entry tear must be distal to LSA, and proximal extent of the proximal landing zone must not be dissected
• For patients with prior replacement of the ascending aorta and/or aortic arch by a surgical graft, there must be at least 2 cm of landing zone proximal to the most distal anastomosis site.
5. Must have appropriate LSA landing zone, defined as:

• Inner diameters of LSA 5-14 mm
• Minimum length of Left subclavian artery is 25 mm
Target branch vessel landing zone must be in native aorta that cannot be severely tortuous, aneurysmal, dissected, heavily calcified, or heavily thrombosed.
6. Must have appropriate distal aortic landing zone, defined as:
• Aortic inner diameters between 18-41 mm
• Landing zone cannot be heavily calcified, or heavily thrombosed.
• For isolated PAU, outer curvature length must be >= 2cm proximal to the celiac artery
• Landing zone in native aorta (Note: Bare stent or graft stent implanted during the procedure before investigational device implantation is allowed)
Note: In Switzerland, Informed Consent can only be signed by subject
Cohort 1 Acute Complicated Type B Aortic dissection (including ULP type) / IMH Cohort
Patients must meet both of the following:
1. Dissection is acute time from symptom onset to dissection diagnosis <=14 days.
2. Must present with at least one of the following:
- Presence of aortic rupture (either free or contained (including hemothorax, increasing periaortic hematoma, or both; or mediastinal hematoma)
- Branch artery occlusion and malperfusion (complete or partial occlusion of a major branch, with or without clinical evidence of ischemia; this includes visceral, renal, and peripheral arterial branches)
- Extension of dissection flap either distally or proximally
- Aortic enlargement: Progressive enlargement of the true, false, or both lumens
- Intractable pain
- Uncontrolled hypertension
IMH patients must meet both of the following:
1. IMH is acute time from symptom onset to IMH diagnosis <=14 days.
2. Must present with at least one of the following:
- Malperfusion
- Periaortic hematoma
- Pericardial effusion with cardiac tamponade
- Persistent, refractory, or recurrent pain
- Rupture
Cohort 2 Non-acute complicated type B Dissection (including ULP type) / IMH and Penetrating aortic ulcer Cohort
Non-acute complicated type B dissection (including ULP type) patients must meet one of the following criteria:
- Presented with high-risk imaging findings. High-risk imaging findings include Maximum aortic diameter > 40mm, False-lumen diameter >20mm, Entry Tear > 10mm; Entry tear on lesser curvature; Increase in total aortic diameter of > 5 mm between serial imaging studies, Bloody pleural effusion. Presented with high-risk imaging features of IMH in uncomplicated type B IMH. High-risk imaging features
include Maximum aortic diameter >47-50 mm; Hematoma thickness >=13 mm; Focal intimal disruption with ulcer-like projection involving the descending thoracic

aorta if develops in acute phase; increasing or recurrent pleural effusions
- Subacute (14 days to 3months) complicated type B Aortic Dissection/IMH (For definition of complicated, please see above cohort 1).
- Pre-emptive TEVAR for subacute (14 days to 3months) or chronic (> 3 months) type B aortic Dissection/IMH. Indications for elective intervention in the chronic setting include aneurysmal dilatation (total >=55-60 mm), increasing rate of diameter (>10 mm/y), chronic ULP-type and/or symptoms (pain, malperfusion).
PAU patients, one of the following criteria must be met:
• PAU with IMH, rupture, or both
• Symptomatic isolated PAU and have persistent pain that is clinically correlated with radiologic findings.
• Asymptomatic isolated PAU present with high-risk imaging features (with one of the following features):
- Maximum PAU diameter >= 13-20 mm
- Maximum PAU depth >= 10 mm
- Significant growth of PAU diameter or depth
- PAU associated with a saccular aneurysm.
- PAU with an increasing pleural effusion

Exclusion criteria

1. Concomitant disease of the ascending aorta or aneurysm of the abdominal aorta requiring repair
2. Aortic lesion resulting from Traumatic Transection
3. Previous endovascular repair of the ascending aorta
4. Surgery within 30 days prior to enrolment with the exception of placement of vascular conduit for access
5. Life expectancy <1 years
6. Myocardial infarction within 6 weeks prior to treatment
7. Stroke within 6 weeks prior to treatment.
8. Pregnant or breastfeeding female
9. Patient has infected aorta and/or an active systemic infection (e.g., infection requiring treatment with parenteral anti-infective medication) that may place the patient at increased risk of endovascular infection.
10. Degenerative connective tissue disease, e.g., Marfan*s or Ehlers-Danlos Syndrome
11. Participation in another drug or medical device study within one year of study enrolment
12. Known history of drug abuse within one year of treatment
13. Tortuous or stenotic iliac and/or femoral arteries preventing introducer sheath insertion and the inability to use a conduit for vascular access
14. Planned coverage of celiac artery
15. Allergic to contrast agents, anesthetics stent graft materials and delivery materials

16. Previous instance of Heparin Induced Thrombocytopenia type 2 (HIT-2) or known hypersensitivity to heparin
17. Patient with a history of a hypercoagulability disorder and/or is currently in a hypercoagulability state
18. Persistent refractory shock (systolic blood pressure <90 mm Hg)
19. Renal failure defined as patients with an estimated Glomerular Filtration Rate (eGFR) <30 (ml/min/1.73 m2) or currently requiring dialysis
20. Contraindications to antiplatelet drugs and anticoagulants
21. Patients aren*t willing to or lacking capacity in the informed consent procedure
22. Investigator judged that not suitable for interventional treatment.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-09-2024
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Cratos Branch Stent Graft System
Registration:	No

Ethics review

Approved WMO

Date:	15-08-2024
Application type:	First submission

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
ClinicalTrials.gov	NCT05874206
CCMO	NL85599.000.23