

Methodology of a prospective, single-arm, multicenter, physician-initiated study to assess the long-term safety and efficacy of the Restorer stent system for the treatment of aorto-iliac lesions. BARISTA trial.

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Abstract

Background

Evidence regarding optimal stent selection in endovascular treatment of aorto-iliac lesions remains inconclusive, particularly in complex TASC C and D disease. Interpretation of existing data is complicated by study heterogeneity and selection bias. Both bare metal stents (BMS) and covered stents (CS) are widely used, yet comparative evidence remains limited. The BARISTA trial aims to prospectively evaluate the safety and efficacy of the Restorer iliac stent system (iVascular) and to compare its outcomes with those reported in contemporary studies assessing covered stents.

Methods

Between July 2022 and June 2024, this prospective multicenter study enrolled 200 patients across 14 Belgian centers. The objective is to assess two-year safety and efficacy outcomes of the Restorer iliac stent system in symptomatic aorto-iliac disease. The primary composite endpoint includes: (1) freedom from target lesion revascularization (TLR), (2) freedom from major amputation, and (3) absence of restenosis within 12 months. TLR is defined as any repeat intervention within the treated segment, including 5 mm proximal and distal to the lesion. Restenosis is defined as $> 50\%$ stenosis on duplex ultrasound with a systolic velocity ratio > 2.4 .

Discussion

By analyzing outcomes in a large prospective cohort and comparing results with contemporary CS data, the BARISTA trial aims to support evidence-based stent selection in aorto-iliac disease.

Trial registration

ClinicalTrials.gov ID: NCT05293002 (2022-03-23)

Background

Background and rationale

Stent based endovascular interventions have become a cornerstone in the treatment of aorto-iliac disease, offering a less invasive alternative to traditional surgical revascularization. Both bare metal stents (BMS) and covered stents (CS) are recommended as first line treatments, each with distinct advantages and limitations. BMS are widely used for their simplicity, effectiveness in maintaining vessel patency, and lower procedural complexity. However, their use in aorto-iliac disease can be limited by issues such as restenosis, particularly in challenging or long lesions. CS, with their protective barrier to

blood flow, have shown promise in reducing restenosis and are particularly beneficial in cases when vessel integrity is compromised. Initially, endovascular treatment demonstrated favorable outcomes in short Trans-Atlantic Inter-Society Consensus (TASC) A & B lesions. With advancements in stent technology, complex aorto-iliac lesions are now increasingly treated through endovascular approaches (1–3).

Current literature does not indicate a significant difference between BMS and CS in treating TASC A and B aorto-iliac lesions. However, the optimal stent choice for more complex TASC C & D lesions remains unclear. While some studies support BMS (4, 5), others report better outcomes with CS (6–8). Historical trials are limited by confounding bias and insufficient clinical evidence to establish a definitive preference. The BARISTA trial aims to generate robust clinical data on the performance of the Restorer iliac BMS system for aorto-iliac disease. Its outcomes will be compared to those of the iliCo trial (NCT05192616), which evaluates the performance of the iCover CS, providing insights into the use of BMS versus CS for TASC A-D aorto-iliac lesions.

Objectives

The aim of the BARISTA clinical trial is to assess the long-term (up to 24 months) safety and efficacy of the Restorer iliac stent system in 200 subjects with aorto-iliac lesions. The study is conducted in a controlled clinical setting post CE-certification and the device is used according to the commercial instructions for use (IFU), with specific focus on treating TASC A, B, C, and D lesions.

Trial design

This is an observational, single-arm, prospective, multicenter study conducted across 14 Belgian sites including a population of 200 patients with a follow-up (FU) period of 2 years. The trial expects a TASC distribution of one-third TASC C and D lesions and two-thirds TASC A and B lesions, reflecting their current incidence.

Clinical data will be collected at screening and enrolment, during the index procedure, at discharge and at the 1-, 6-, 12- and 24- month follow-up visits. Adverse events will be monitored from enrolment through study completion or study exit. Seriousness, severity and relationship to study lesion, device and procedure will be assessed.

Methods: Participants, interventions and outcomes

Study setting

The study is conducted across 14 Belgian hospitals, listed below. CENSORED

Eligibility criteria

Patients must meet the following inclusion criteria to be eligible for the study: 1) Provide written informed consent prior to study enrolment, 2) be willing to comply with study specific follow-up evaluations, 3) be male or a non-pregnant female aged ≥ 18 years, 4) have a stenotic or occlusive lesion in the aorto-iliac arteries, suitable for stenting with the Restorer stent, 5) have an estimated life expectancy ≥ 2 years, 6) have a Rutherford clinical category (RCC) score of 2–4, 7) present angiographic evidence of (re)stenosis $> 50\%$ or an occlusion that can be crossed with standard guidewire manipulation, and 8) have a patent common femoral artery (CFA) with a patent deep and/or superficial femoral artery, confirmed by angiography.

Patients will be excluded if they meet any of the following criteria: 1) history of coagulation disorders, 2) presence of an aneurysm immediately adjacent to the study lesion, 3) study lesion extending into the CFA or extending > 1 cm into the distal aorta, 4) presence of fresh thrombus formation, 5) acute limb ischemia, 6) presence of a systemic infection or immunocompromised status, 7) existing stent in the target vessel placed before study enrolment, 8) use of alternative therapies (e.g., atherectomy, drug eluting devices, laser) during the study procedure, 9) known blood disorders, including hypercoagulable state, bleeding diathesis, coagulopathy or platelet count outside range (80.000–500.000/ μl), 10) contraindication to antiplatelet, anticoagulant, or thrombolytic therapy, 11) hypersensitivity to stent material (CoCr L605) or any contraindications listed in the device Instructions for Use (IFU), 12) comorbidities preventing treatment or follow-up, as deemed by the investigator, 13) non-manageable allergy or hypersensitivity to contrast agents, 14) inadequate treatment of a potential inflow lesion, 15) simultaneous participation in another clinical study where the primary endpoint has not been reached, and 16) any planned intervention within 30 days after the index procedure.

Who will obtain informed consent?

The principal investigator at each clinical site, who is experienced in the informed consent process, is responsible for obtaining written consent prior to enrolment. The consent process follows the principles of the World Medical Association (WMA) Declaration of Helsinki.

Additional consent provisions for data and biological specimens

Not applicable (N/A): This study does not require the collection and use of participant data and biological specimens in ancillary studies.

Interventions

Choice of comparators

N/A: This is not a comparative study.

Intervention description

Vascular access is obtained according to the investigator's standard clinical practice. A guidewire must cross the entire lesion and reach the distal vessel beyond the target lesion. Only approved conventional mechanical guidewires may be used during the procedure. Either intraluminal or subintimal passage is permitted, following well established endovascular techniques. Once the lesion has been successfully crossed, diagnostic angiography of the lesion area and distal run-off is performed. The following angiographic measurements are collected: vessel diameter, percentage stenosis and lesion length. The angiographic data will be made available to the Clinical Event Committee (CEC) for independent review and assessment if required.

Procedures for stent implantation are based on the Restorer Instructions for Use (IFU). At the physician's discretion, at least one Restorer stent must be implanted. While there is no strict limit on the number of stents, it is recommended to select the stent length that best matches the lesion length. Only the Restorer stent can be used to treat the study lesion. Outflow iliac lesions may be treated according to physician's discretion. Pre- and post-dilation are performed at the physician's discretion. All aorto-iliac study lesions must be treated in a single session; staged interventions are not permitted. Distal blood flow must be monitored before and after the procedure, to confirm the absence of distal embolization. All outflow-limiting lesions must be treated in accordance with the hospital's standard treatment protocols. Hemostasis is achieved through manual compression or the use of a closure device.

Criteria for discontinuing or modifying allocated interventions {11b}

Investigators are required to adhere strictly to the signed investigator agreement and study protocol. Except in an emergency, prior approval by the sponsor is required for changes in or deviations from the plan. If modifications or deviations affect the scientific integrity of the study or affect the rights, safety, or welfare of subjects, the Sponsor and the reviewing Ethics Committee (EC) must be notified to obtain approval.

Strategies to improve adherence to interventions

Continuous remote monitoring improves adherence to the protocol.

Relevant concomitant care permitted or prohibited during the trial

During hospitalization and follow-up, the recommended concomitant medication includes: Clopidogrel at a dose of 75 mg daily for a minimum of one month, and aspirin at a dose of 75–300 mg daily, continued indefinitely. In cases where non-vitamin K antagonist oral anticoagulants (NOACs) or coumarins (anticoagulants) are prescribed, the combination with clopidogrel 75 mg daily is recommended for at least one month.

Provisions for post-trial care

After the procedure, the required tests and assessments include: angiography immediately post-procedure from the aortic bifurcation to the foot or feet; physical examination before discharge; and a Color Flow Doppler Ultrasound (Duplex scanning), if this aligns with the standard of care (SOC) at the participating center.

Outcomes

The primary endpoint of the BARISTA trial is freedom from target lesion revascularization (TLR), major amputation and restenosis within 12 months. TLR is understood as any re-intervention to restore or maintain patency of the study lesion, including 5 mm proximal and distal to the edge of the treated lesion. Restenosis is defined as significant stenosis on duplex ultrasound ($> 50\%$ stenosis, systolic velocity ratio > 2.4).

The secondary endpoints include: 1) technical success (explained as final residual stenosis $< 30\%$ on angiography), 2) primary patency rate (PP) at 6-, 12- and 24 months post procedure. PP is defined as freedom from target lesion restenosis (luminal diameter reduction $> 50\%$ and peak systolic velocity ≥ 2.4) and TLR. 3) Freedom from major adverse events (MAEs) at 1-, 12- and 24 months. MAEs include device/procedure related death, clinically driven TLR (CD-TLR) and major index limb amputation. 4) Stent occlusion rate at discharge, 1-, 6-, 12- and 24 month follow-up, 5) ankle brachial index (ABI) evolution at 1-, 6-, 12-, and 24 month follow up compared to baseline, 6) freedom from TLR at 1-, 6- and 24 months follow-up, 7) clinical success at 6-, 12-, and 24 month follow-up (defined as RCC improvement of at least one class compared to baseline RCC values), 8) change in Walking Impairment Questionnaire (WIQ) score and Quality of Life Questionnaire (EQ-5D) score between 1-, 6- 12- and 24 month follow-up and baseline values, 9) limb salvage (freedom from above the ankle target limb amputations) at 6-, 12- and 24 months, 10) mortality at 6-, 12- and 24 months and 11) safety (composite of mortality, TLR, study lesion perforation and macroscopic distal embolization) at 6-, 12-, and 24 months.

Participant timeline

The participant timeline is detailed in in Table 1.

Table 1

Participant timeline. Abbreviations: PIC = patient informed consent; ABI = ankle brachial index; WIQ = walking impairment questionnaire; EQ5D = Quality of Life Questionnaire; PSVR = peak systolic velocity ratio.

PIC	Pre	Procedure	Post	FU 1M (± 7 days)	FU 6M (± 30 days)	FU 12M (± 30 days)	FU 24M (± 30 days)
	X						
Inclusion and exclusion criteria	X	X					
Demographics	X						
ABI & Rutherford	X			X	X	X	X
Medication	X	X	X	X	X	X	X
Physical examination	X		X	X	X	X	X
WIQ & EQ5D	X			X	X	X	X
Medical history	X						
Angiogram		X					
Procedural details		X					
Duplex with PSVR				X	X	X	X
Adverse Events		X	X	X	X	X	X

Sample size

The clinical investigation will enroll a minimum of 200 patients across approximately fourteen Belgian sites. This sample size is the minimum necessary to compare the safety and efficacy of the balloon-expandable Restorer BMS (study device) with the iCover CS from the iliCo trial, which also targets aorto-iliac TASC A-D lesions.

Recruitment

Before enrollment in the clinical trial, all patients will be assessed by their physician to determine if they meet the general inclusion criteria. Since the TASC-II classification describes the overall characteristics of the aorto-iliac segment, each patient may only be included once in the study. Prior to enrollment and the collection of personal medical data, written informed consent must be obtained in accordance with the WMA Declaration of Helsinki. A patient is considered enrolled in the study if they meet all inclusion and exclusion criteria and after successful guidewire passage through the study target lesion.

Assignment of interventions: allocation

Sequence generation

N/A: all patients receive the same treatment.

Concealment mechanism

N/A: all patients receive the same treatment.

Implementation

N/A: all patients receive the same treatment.

Assignment of interventions: Blinding

Who will be blinded

N/A: This is not a randomized clinical trial, so blinding is not required.

Procedure for unblinding if needed

N/A: This is not a randomized clinical trial, so blinding is not required.

Data collection and management

Plans for assessment and collection of outcomes

Physical examinations will be carried out and documented at baseline (inclusion), prior to discharge, and at 1-, 6-, 12-, and 24-month follow-up. Standard techniques and assessments will be used per local clinical practice. The Clinical Categories of Chronic Limb Ischemia will be assessed at inclusion and at each scheduled follow-up (1-, 6-, 12-, and 24-months). A detailed classification of these categories is provided in Table 2

Table 2
Clinical Categories of Chronic Limb Ischemia. Abbreviations: AP = Ankle pressure.

Category	Clinical description	Objective Criteria
0	Asymptomatic No hemodynamically significant occlusive disease	Normal Treadmill*/stress test (*5 minutes at 2 mph on a 12° incline)
1	Mild claudication	Completes treadmill exercise (> 250 m), Post-exercise AP is > 50 mm Hg, but > 25 mm Hg lower than normal
2	Moderate claudication	Unable to complete treadmill (100–250 m)
3	Severe claudication	Treadmill test failed (< 100 m) Post-exercise ankle pressure < 50 mm Hg
4	Ischemic Rest Pain	Resting AP ≤ 40 mm Hg, flat or barely pulsatile ankle or metatarsal Doppler recording, Toe pressure < 30 mm Hg
5	Minor Tissue Loss Non-healing ulcer, gangrene with diffuse pedal ischemia	Resting AP ≤ 60 mm Hg, flat or barely pulsatile ankle or metatarsal Doppler recording, Toe pressure < 40 mm Hg
6	Major Tissue Loss Extending above transmetatarsal level, functional foot no longer salvageable	Same as Category 5

Duplex scanning will be performed at 1-, 6-, 12-, and 24-month follow-up visits. B-mode image data will be collected in transverse and sagittal views. The maximum Peak Systolic Velocity (PSV) will be recorded from the following segments: proximal and distal to the investigated stents (unilateral or bilateral as applicable). PSV ratios will be calculated by dividing the highest velocity PSV by the maximum PSV at a site immediately proximal to the increased velocity. end diastolic velocity will be calculated if the PSV ratio is greater than 2.4.

Conventional angiography will be used to identify the target lesion, confirming its suitability for trial inclusion and assessing procedural steps. Pre-procedural and post-procedural images will document lesion characteristics (e.g., location, length, stenosis percentage, outflow condition and condition of adjacent stenosis) and immediate post-procedural success. Pre- and post-procedure run off angiography (from aorta to foot) will be to assess distal embolization.

Plans to promote participant retention and complete follow-up

There are no specific retention strategies to ensure complete follow-up. Any protocol deviations or participant withdrawals will be recorded in the electronic case report forms (eCRF).

Data management

Patient data will be captured electronically in the eCRF and monitored for quality assurance.

Confidentiality

Subject confidentiality will be maintained, ensuring data traceability to source documents via a unique subject identification code.

Data access by third parties (e.g., regulatory audits) will require confidentiality assurance. Data protection will comply with Directive 95/46/EC, and as of 25 May 2018, the General Data Protection Regulation (EU 2016/679). Personal data storage at participating sites will adhere to Belgian law.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use

Not applicable: There are no plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis for this or future trials.

Statistical methods

Analysis of primary and secondary outcomes

The study will enroll a sample size of 200 patients to compare the safety and efficacy of the balloon expandable Restorer stent system against the covered iCover stent evaluated in the iliCo study, involving aorto-iliac TASC A-D lesions.

Descriptive data summaries will be provided. Kaplan Meier estimates will be generated for all time-dependent events from the procedure date through the 24-month follow-up. Subgroup analyses will be conducted according to TASC classification, lesion location, calcification, gender, diabetes and Rutherford category, assessing clinical outcome, patency and TLR at 12 and 24 months. Log rank tests with p-values of < 0.05 will indicate statistical significance.

Interim analyses

An interim analysis will be performed when one-third of the study population is enrolled ($N = 67$). With an estimated balloon-expandable BMS composite event rate of 10% and an anticipated 10% loss to follow-up, this sample size will provide a two-sided 95% confidence interval with a precision of 8.7%. A maximum composite event rate of 18.7% is considered acceptable, aligning with published data on equivalent treatments.

Methods for additional analyses (e.g. subgroup analyses)

Stratification will be performed based on pre-procedural risk factors, Rutherford-classification, TASC-Classifications and lesion characteristics. The log rank test will be used to compare the outcomes, with p-values < 0.05 considered significant. Peri- and post-procedural complications (< 24 hours) will also be evaluated and documented.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

Not applicable: No statistical methods will be used to handle protocol non-adherence or missing data.

Plans to give access to the full protocol, participant level-data and statistical code

Not applicable: There are no plans for granting public access to the full protocol, participant-level dataset, and statistical code.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee

Censored

Composition of the data monitoring committee, its role and reporting structure

Qualified monitors from iD3 Medical will conduct on-site and remote monitoring visits to ensure investigator compliance with the study protocol and agreements. Sites will receive notification prior to each visit. The investigator and/or co-investigator and other appropriately trained study staff are expected to be available on the day of the visit to address any queries.

The study progress will be monitored through:

- • Verification the completed eCRF matches source documents, with resolution of discrepancies. Monitors must have direct access to complete source documents and medical records, including electronic medical records, for eCRF data verification, including AE data.
- • Periodic on-site visits and remote monitoring of study data.

- Ongoing telephone and/or email communications between the investigator/site and the assigned site monitors.

Regular on-site and remote monitoring visits will ensure compliance with the protocol, regulatory requirements, and EC procedures for approval of protocol changes. These visits will confirm site acceptability, proper record-keeping, regulatory reporting, inventory control, and investigator adherence to study activities.

iD3 Medical will assess any protocol deviations and reserves the right to remove investigators or sites from the study for issues of non-compliance with the protocol or regulatory requirements.

Adverse event reporting and harms

All adverse events (AEs) and adverse device effects (ADEs) will be monitored from enrolment through the 24-month follow-up. AEs will be classified as mild, moderate, severe, and serious. All AEs and ADEs must be recorded on the CRFs provided. Each AE report must include a description, start and stop dates, device relation, actions taken, and outcomes, along with the Investigator's assessment of the relationship between the AE and the study treatment. Pre-existing conditions at enrolment will not be reported as AEs unless there is an increase in severity.

Frequency and plans for auditing trial conduct

Study sites may be inspected or audited by iD3 Medical, its representatives or regulatory agencies at any time. Investigators will receive prior notice of such visits.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees)

N/A: there are no plans for communicating important protocol modifications to relevant parties.

Dissemination plans

Publications will adhere to internationally recognized scientific and ethical standards for authorship and research dissemination.

Discussion

Recent studies and meta-analyses have provided valuable insights into the comparative effectiveness of BMS and CS in aorto-iliac disease. However, results – particularly in complex TASC C and D lesions- must be interpreted with caution due to potential bias (9). Data suggest that while both stent types are safe and effective, selection depends on the lesion characteristics, procedural considerations and the patient risk factors. The BARISTA trial and iliCo trials will generate extensive data on the safety and

efficacy of the Restorer and iCover, enabling direct comparison of BMS and CS in TAC A-D aorto-iliac disease and guiding future treatment strategies.

Abbreviations

ABI	Ankle brachial index	MAE	Major Adverse Event
ADE	Adverse Device Event	NOAC	Non Vitamin K antagonist Oral Anticoagulants
AE	Adverse Event	N/A	Not Applicable
AIOD	Aortoiliac Occlusive Disease	PIC	Patient Informed Consent
AP	Arterial Pressure	PP	Primary Patency
BMS	Bare Metal Stent	PSV	Peak Systolic Velocity
CEC	Clinical Event Committee	PSVR	Peak Systolic Velocity Ratio
CFA	Common Femoral Artery	RCC	Rutherford Clinical Category
CS	Covered Stent	SOC	Standard Of Care
EC	Ethics Committee	TASC	Trans-Atlantic Inter-Society Consensus
eCRF	Electronic Case Report Forms	TLR	Target Lesion Revascularization
EQ5D	Quality Of Life Questionnaire	WIQ	Walking Impairment Questionnaire
IFU	Instructions For Use	WMA	World Medical Association

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