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Safety and performance on ECC cannulas

Submission date 04/11/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 17/11/2025	**Overall study status** Ongoing	
Last Edited 12/11/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
This study will assess new Eurosets cannulae used for extracorporeal circulation and compare them with currently marketed Maquet HLS cannulae.

Who can participate?
Patients aged 18 years and older requiring extracorporeal circulation.

What does the study involve?
The investigation is divided into two phases.
• In Phase I, 22 patients will be enrolled to confirm safety.
• If safety is demonstrated, Phase II will enrol about 100 patients in total to test whether Eurosets cannulae are not inferior to Maquet cannulae regarding performance.
Performance will be measured as blood drainage and reinfusion pressures during extracorporeal circulation.
Patients requiring veno-arterial extracorporeal circulation will be randomized to receive either Eurosets or Maquet cannulae.
Data will be collected on cannula pressures, blood lactate, procedure duration, ease of use, integrity of the cannulae, and hospital stay.

What are the possible benefits and risks of participating?
There are possible clinical benefits associated with the use of the devices under investigation in terms of clinical performance and biocompatibility parameters compared to the currently available cannulas.

No additional risks attributable specifically to the devices under investigation are foreseen compared to the standard ECC procedure. The risks associated with the use of other commercially approved devices are managed and mitigated according to the standard practice in place at the investigational sites for the procedures to be implemented in this clinical investigation.

Where is the study run from?
Eurosets S.r.l.

When is the study starting and how long is it expected to run for?
July 2024 to December 2026

Who is funding the study?
Eurosets S.r.l.

Who is the main contact?
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
EUDAMED IT-25-03-051856, Study Code CI23_TD62

Study information

Scientific Title
Two-phase clinical investigation of cannulas for extracorporeal circulation: safety and performance evaluation

Study objectives
Primary Objectives:
1. Phase I: Pilot Stage
Primary objective
Evaluate the safety of Drainage and Return Cannulas.
2. Phase II: Pivotal Stage
Primary objective
Evaluate the non-inferiority of the Drainage and Return Cannulas' performance compared to the Control Cannulas.

Secondary Objectives:
1. Phase I: Pilot Stage
Secondary objective
Confirm the standard deviation and non-inferiority margin parameters for performance evaluation in Phase II.
2. Phase II
Secondary objectives
Evaluate the adequacy of tissue perfusion.
Evaluate the patient's metabolic condition in real time
Evaluate the duration of the ECC procedure.
Evaluate cannulation user friendliness.
Evaluate decannulation user friendliness.
Evaluate the integrity of the Drainage and Return cannulas at decannulation time.
Evaluate the presence of clots or thrombi in the Drainage and Return cannulas at decannulation time.
Evaluate hospital stay.

Safety objective
Confirm the safety of Drainage and Return Cannulas

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/05/2025, Ethics Committee "Lombardia 6" (V.le Golgi 19, Pavia, 27100, Italy; +39 0382.5011; comitato.bioetica@smatteo.pv.it), ref: 2024-3.11/539

Study design
Pre-market two-phase pilot and non-inferiority randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Safety

Health condition(s) or problem(s) studied
Patients requiring veno-arterial extracorporeal circulation

Interventions

The research protocol for evaluating Drainage and Return Cannulas is structured as a comprehensive two-phase study, the first aimed at ensuring safety and the second aimed at evaluating the performance of the investigational devices.

Phase I
• Clinical investigation Type: Pre-market, pilot, interventional, randomized, stratified by BSA, multicenter.
• Participants: 22 patients.
• Outcome Measures: Safety (primary), standard deviation, and non-inferiority margin for performance (secondary).
• Randomization: 1:1 between investigational Drainage and Return Cannulas and CE-marked comparator Cannulas in the same patient.

Phase II
• Clinical investigation Type: Pre-market, pivotal, interventional, randomized, stratified by BSA, non-inferiority, multicenter.
• Participants: Considering a drop-out rate of 15%, 100 subjects (50 subjects per group) will participate in the Clinical investigation between Phase I and Phase II. This number is a pure estimation, since the actual sample size will be recalculated based on the result of Phase I analysis.
• Outcome Measures: Safety, performance of Drainage and Return Cannulas.
• Randomization: 1:1 between investigational Drainage and Return Cannulas and CE-marked comparator Cannulas in the same patient.

The randomisation ensures unbiased allocation of subjects between study arms and will be implemented as follows:
• Subjects will be randomly assigned in a two-arm 1:1 allocation (Investigational vs. Control), with 22 subjects in Phase I (11 per arm) and approximately 78 subjects in Phase II (39 per arm, depending on Phase I outcomes). Randomisation will be stratified by Body Surface Area (BSA), using two predefined categories (1.40–1.95 m^2 and 1.96–2.50 m^2)
• Block size: 4 subjects per block, ensuring that within each block, 2 subjects are assigned to the investigational arm and 2 to the control arm, maintaining a balanced distribution.
• The randomisation list will be generated and implemented within a secure electronic Case Report Form (eCRF) system, which uses a computer-based pseudo-random algorithm to ensure full unpredictability and reproducibility of the allocation sequence. The eCRF automatically assigns each subject to the appropriate treatment arm at enrolment while maintaining allocation concealment. All randomisation events are documented in the system audit trail, capturing date, time, and user identification to guarantee traceability and data integrity across all sites
This process guarantees an unbiased allocation and preserves the integrity of the study design across all sites.

• Arm A (investigational): Eurosets multistage femoral venous drainage cannulae (EUVFMULTI26C, EUVFMULTI28C) and return cannulae (EURET1716C, EURET1718C, EURET1720C).
• Arm B (control): Maquet HLS venous cannulae (BE-PVL 2555, BE-PVL 2955) and arterial cannulae (BE-PAL 1723, BE-PAL 2123).
Patients randomized 1:1. ECC management per local standard of care. Continuous monitoring of flow and cannula pressure.

Intervention Type
Device

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
Eurosets multistage femoral venous drainage cannulae (EUVFMULTI26C, EUVFMULTI28C) and return cannulae (EURET1716C, EURET1718C, EURET1720C).

Primary outcome(s)
1. Phase I (Safety): Number and type of adverse events related to the investigational device to be collected via eCRF from investigator reports, clinical assessments, and patient medical records during ECC and up to 2 days post-weaning.
2. Phase II (Non-inferiority): This phase has two co-primary endpoints:
2.1. Multistage Venous Femoral Cannulae – Drainage Pressure Performance measured using continuous ECC circuit pressure transducers recorded in the eCRF at 1h (V1), 6h (V2), regular intervals (VxM/VxA), and pre-weaning (Vy)
2.2. Return Cannulae – Reinfusion Pressure Performance measured using continuous ECC circuit pressure transducers recorded in the eCRF at 1h (V1), 6h (V2), regular intervals (VxM/VxA), and pre-weaning (Vy)

Key secondary outcome(s))
1. Phase I: Pilot Stage. Drainage and reinfusion pressures relative to blood flow rate measured using ECC monitoring system and eCRF during the ECC procedure (V1–Vy)

2. Phase II: Pivotal Stage.
2.1. Tissue Perfusion: Blood lactate levels measured using blood sample analysis from arterial line at baseline (V0), 1h (V1), 6h (V2), and at ECC end (Vy)
2.2. ECC Procedure Duration: Total procedure time (hours/minutes) measured using ECC start, and weaning times recorded in eCRF at pre-weaning (Vy)
2.3. User Friendliness: Cannulation and decannulation difficulty measured using a 5-point Likert scale completed by the physician at V1 (cannulation) and at decannulation (Vy)
2.4. Cannula Integrity: Structural integrity (Yes/No) measured using a visual inspection at decannulation (Vy)
2.5. Presence of Clots or Thrombi: Evidence of clot formation (Yes/No) measured using a visual inspection at decannulation (Vy)
2.6. Cannulation Site Complications: measured using clinical examination and medical record review throughout ECC and at follow-up visits (Vz, Vw)
2.7. Hospital Stay: measured using medical records and eCRF data at discharge (Vw)

3. Safety Endpoints
3.1. Clinical Parameters Monitoring measured using Standard patient monitoring devices during ECC and at all visits (V0–Vw)
3.2. Device Performance measured using Operator report and eCRF documentation at pre-, during, and post-cannulation (V0–Vy)
3.3. Adverse Events measured using Investigator assessment and eCRF report from baseline (V0) to end of study (Vw)
3.4. Concomitant Medications measured using a review of patient records and eCRF documentation from screening (V0) through follow-up (Vw)

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Written informed consent or emergency enrolment under EU Reg. 536/2014, Art. 35.
2. Age ≥ 18 years
3. Body surface area 1.4–2.5 m²
4. Requirement for VA-ECC (including VA-ECMO)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Chronic hemodialysis
2. Diabetes mellitus
3. Hematological disease or history of thrombophilia
4. Pregnancy or breastfeeding
5. Active/metastatic malignancy
6. Severe CNS injury or intracranial hemorrhage
7. Anatomical abnormalities preventing participation
8. Uncontrolled active bleeding before ECC
9. Severe clinical condition interfering with participation
10. Participation in another interventional trial within 30 days
11. Advance directives excluding ECMO/ECC
12. Inability to comply with follow-up

Date of first enrolment
25/10/2025

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
Italy

Study participating centre
Fondazione IRCCS Policlinico San Matteo
V.le C. Golgi 19
Pavia
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Study participating centre
IRCCS Ospedale San Raffaele
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Sponsor information

Organisation
Eurosets (Italy)

ROR
https://ror.org/02pqj5664

Funder(s)

Funder type
Industry

Funder Name
Eurosets S.r.l.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality reasons; only aggregated data will be disclosed as per the publication and dissemination plan. However, access to the full datasets will be granted to competent authorities upon request for inspection purposes.

IPD sharing plan summary

Published as a supplement to the results publication