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Total flow medical femoral arterial cannula evaluation during cardiopulmonary bypass

Submission date
17/10/2025

Recruitment status
No longer recruiting

Registration date
21/10/2025

Overall study status
Completed

Last Edited
21/10/2025

Condition category
Surgery

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Femoral arterial cannulation is used as part of the heart-lung machine during heart surgery, but it can lead to reduced blood flow to the leg, resulting in potential complications. Current solutions to maintain limb perfusion are limited and can add procedural complexity. The Total Flow Medical Femoral Arterial Cannula is a novel device designed to provide sufficient blood flow to the entire body, including the leg. Preclinical testing has shown promising results supporting its safety and performance. This study will evaluate the device in a clinical setting.

Who can participate?
Adult patients undergoing elective minimally invasive heart surgery requiring femoral arterial cannulation.

What does the study involve?
Eligible adults undergoing elective minimally invasive cardiac surgery requiring femoral arterial cannulation will be enrolled after informed consent. The Total Flow Medical Femoral Arterial Cannula will be used according to its instructions for use, with procedural data, intraoperative hemodynamic and perfusion metrics being collected.

What are the possible benefits and risks of participating?
Participants may not directly benefit from taking part. Risks are similar to those of standard femoral cannulation and cardiopulmonary bypass, including bleeding, vascular injury, limb ischemia, or infection.

Where is the study run from?
Foothills Medical Centre in Calgary, AB, Canada.

When is the study starting and how long is it expected to run for?
June 2025 to March 2026. The study is anticipated to start enroling in October 2025 and finish by March 2026.

Who is funding the study?
Total Flow Medical Limited, Canada.

Who is the main contact?
Matt Rieger, PhD, ACRP-CP, matt.rieger@ucalgary.ca

Contact information

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Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Total flow medical femoral arterial cannula evaluation during cardiopulmonary bypass

Acronym
TACTIC

Study objectives
To assess the technical performance and clinical use of the Total Flow Medical Femoral Arterial Cannula in subjects undergoing minimally invasive cardiac surgery on cardiopulmonary bypass.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 25/07/2025, Co-joint Health Research Ethics Board (CHREB) (2500 University Drive N. W., Calgary, T2N 1N4, Canada; +1 (403) 220-2297; chreb@ucalgary.ca), ref: REB25-1197

Primary study design
Interventional

Study design
Single-arm non-randomized prospective

Study type(s)
Safety

Health condition(s) or problem(s) studied
Femoral arterial cannulation during minimally invasive cardiac surgery

Interventions
Participants undergoing elective minimally invasive cardiac surgery requiring femoral arterial cannulation will be enrolled after written informed consent. During surgery, the Total Flow Medical Femoral Arterial Cannula will be used as an arterial delivery cannula according to the device's instructions for use. Procedural data (line pressures, flow rate, mean arterial pressure and limb near-infrared spectroscopy [NIRS] perfusion values) will be collected intraoperatively. Post-operative monitoring will continue through discharge, with a single follow-up assessment at 30 days.
Total duration of participation: approximately 30 days per subject (intraoperative through 30-day follow-up).
Total study duration: expected enrollment and follow-up period of ~5 months.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Total flow medical femoral arterial cannula

Primary outcome(s)
The technical performance of the Total Flow Medical femoral arterial cannula will be measured by incorporating observations made throughout the bypass period, using a structured procedural evaluation form completed by the surgical and perfusion team based on the device Instructions for Use (IFU); this includes assessment of handling characteristics (insertion, use, and withdrawal), clinician-determined adequacy of perfusion, and objective intraoperative parameters such as cannula flow rate (L/min), arterial line pressure (mmHg), mean arterial pressure (MAP), and limb near-infrared spectroscopy (NIRS) values, immediately after cardiopulmonary bypass

Key secondary outcome(s)
Safety events are measured using data collected from operative reports, medical records, and electronic case report forms (eCRFs), including vascular injury, bleeding, limb ischemia, or other device- or procedure-related adverse events, at hospital discharge (≤5 days) and at 30-day follow-up

Completion date
30/03/2026

Eligibility

Key inclusion criteria
Patients undergoing elective minimally invasive cardiac surgery (MICS) with clinical indications for femoral cannulation for cardiopulmonary bypass.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients undergoing complex cardiac procedures beyond single-valve surgery, emergency surgery, or requiring non-femoral cannulation
2. Significant femoral artery disease or anatomy potentially unsuitable for the investigational cannula
3. High-risk clinical conditions (e.g., stroke, shock, infection, renal failure)

Date of first enrolment
27/10/2025

Date of final enrolment
10/02/2026

Locations

Countries of recruitment
Canada

Study participating centre
Libin Cardiovascular Institute, Foothills Medical Center
University of Calgary
3330 Hospital Drive NW
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Sponsor information

Organisation
Total Flow Medical Limited

Funder(s)

Funder type
Industry

Funder Name
Total Flow Medical Limited

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date