Simultaneous Measurement of EpicArdial and Microvascular ResisTance via Angiographic FLOW Study (SMARTFLOW)

First published: 18/06/2026

Last updated: 23/06/2026

Study Planned

Administrative details

EU PAS number

EUPAS1000001032

Study ID

1000001032

DARWIN EU® study

No

Study countries

- Belgium
- France
- United Kingdom
- United States

Study description

Prospective, single-arm, observational multicenter study of patients with suspected coronary artery disease (CAD) undergoing clinically indicated invasive coronary angiography with physiological assessment. The study is designed to evaluate performance of the AngioAI+ software in a retrospective manner. The investigational AngioAI+ device will not inform clinical decisions amid the study.

Primary endpoint 1 – FFR; Primary endpoint 2- CMD.

Eligibility and Cohorts Adult patients with acute or chronic coronary syndromes referred for invasive coronary angiography with clinically indicated physiologic assessment. All patients will undergo clinically indicated invasive coronary angiography with physiological assessment according to Standard of Care (SoC).

Two prospective cohorts will be included:

1. Cohort 1. Patients with intermediate coronary artery stenosis (30-90% diameter stenosis) with clinically
indicated FFR assessment.
2. Cohort 2. Symptomatic patients with NOCAD (<30% stenosis) with clinically indicated microvascular
assessment.

Clinical Exclusion Criteria: (1) Patients presenting with ST-elevation acute coronary syndrome, (2) Prior myocardial infarction in the target vessel, (3) Stent implantation in the target vessel within the last 12 months, (4) Previous coronary artery bypass grafting (CABG), (5) Previous heart valve surgery, (6) Previous heart transplantation, (7) Moderate-to-severe valvular disease, (8) Left ventricular ejection fraction (EF) ≤45%, (9) Hemodynamic instability or cardiogenic shock.

Angiographic Exclusion Criteria: (a) Left main stenosis ≥50%, (b) Chronic total occlusion in target vessel, (c) CTO in a non-target vessel, (d) Less than thrombolysis in myocardial infarction (TIMI) 3 flow in target vessel, (e) Target vessel receiving collaterals, (f) Inadequate coronary angiographic images (g) Ostial lesions, and (h) Severe tortuosity.

Study status

Planned

Research institutions and networks

Institutions

Toulouse University Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Guy's and St Thomas' NHS Foundation Trust

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Cardiovascular Center OLV Aalst, Belgium

Cardiovascular Research Foundation (New York, New York USA)

Contact details

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Study timelines

Date when funding contract was signed

Planned: 01/07/2026

Study start date

Planned: 01/07/2026

Data analysis start date

Planned: 01/08/2027

Date of final study report
Planned: 01/01/2028

Sources of funding

- Other

More details on funding

Sponsor is a for-profit corporation in the United States.

Study protocol

SMARTFLOW_Protocol_APRIL2026_synopsis_for_publication.pdf (156.95 KB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Medical device

Study type:

Non-interventional study

Scope of the study:

Method development or testing

Data collection methods:

Secondary use of data

Study design:

The SMARTFLOW study is a prospective, observational, single-arm, multicentric, and international study with centralized data collection. Angiographic and physiological data will be analyzed in a blinded fashion by an independent core laboratory.

Main study objective:

The SMARTFLOW study aims to determine the accuracy of a novel angiography-based software AngioAI+ (developed by AngioInsight Inc.), for assessing FFR and CMD. By validating this technology against invasive physiological measurements, we seek to establish its role as a reliable, noninvasive device which aids in the comprehensive evaluation of coronary physiology assessment. The ability to assess both epicardial and microvascular function using a single imaging modality could dramatically improve diagnostic accuracy, therapeutic guidance, and overall patient outcomes.

Study Design

Non-interventional study design

Case-only

Study drug and medical condition

Medical condition to be studied

Stenosis

Non-obstructive cardiomyopathy

Population studied

Short description of the study population

Adult patients with acute or chronic coronary syndromes referred for invasive coronary angiography with clinically indicated physiologic assessment.
Eligibility and Cohorts Adult patients with acute or chronic coronary syndromes referred for invasive coronary angiography with clinically indicated physiologic assessment. All patients will undergo clinically indicated invasive coronary angiography with physiological assessment according to Standard of Care (SoC).
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Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)

Estimated number of subjects

650

Study design details

Setting

Qualified clinicians within the catheterization lab to provide an assessment of stenosis and blood flow.

Comparators

Single arm, prospective study of imaging.

Outcomes

Primary endpoints 1 - FFR: Per-vessel diagnostic performance (i.e., sensitivity and specificity) of AngioAI+ FFR for identifying flow-limiting lesions, using measured FFR as the reference standard.
Primary endpoints 2- CMD: Diagnostic performance (i.e., sensitivity and specificity) of AngioAI+ for detecting CMD in patients with non-obstructive CAD (NOCAD) using invasive coronary flow reserve (CFR) derived from continuous thermodilution as reference.

Data analysis plan

The study is powered to demonstrate the diagnostic accuracy of AngioAI+ with a pre-defined performance goal of ≥80% sensitivity and specificity for diagnosing hemodynamically significant artery stenosis using FFR (cut-off ≤ 0.80) as reference. Assuming a sensitivity of 90%, a one-sided alpha of 0.025, and 90% power, 137 vessels with a positive FFR must be included to ensure that the lower limit of the two-sided 95% confidence interval for sensitivity is ≥80%. Assuming a specificity of 90%, a one-sided alpha of 0.025, and 90% power, 137 vessels without a positive FFR must be included to ensure that the lower limit of the two-sided 95% confidence interval for specificity is ≥80%.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown