Pressure Microcatheter vs Pressure Wire for Clinical Decision Making and PCI optimization

Published: 04-01-2023
Last updated: 21-12-2024

The primary objective of the study is to assess the safety and efficacy of a pressure microcatheter guided treatment decision and PCI optimization compared to a pressure wire based strategy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51757

Source
ToetsingOnline

Brief title
INSIGHTFUL-FFR

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Stenosis in the coronary arteries and spasm of the heart (angina pectoris)

Research involving
Human

Sponsors and support

Primary sponsor: CoreAalst BV

Source(s) of monetary or material Support: Insight Lifetech,Insight Lifetech;de fabrikant van de drukmicrocatheter

Intervention

Keyword: Acute Coronary Syndrome, Coronary Artery Disease, Coronary Disease, Percutaneous Coronary Intervention (PCI)

Outcome measures

Primary outcome

Rate of major adverse cardiovascular events (MACE) defined as the combined rate of all-cause death, myocardial infarction (MI), and unplanned revascularization between pressure microcatheter and pressure wire strategies at 12-month follow-up.

Secondary outcome

1. Resource utilization i.e., number of pressure catheters/wires and procedural time needed to complete the procedure.

2. Procedure time in a pressure microcatheter and pressure-wire guided strategies: the time from first to the last angiography.

3. In patients undergoing PCI, resource utilization (number of catheters/wires) between a pressure PIOS-MC and PIOS-PW strategies in patients undergoing PCI.

4. In patients undergoing PCI, the procedural time between a pressure PIOS-MC and PIOS-PW strategies.

5. In patients undergoing PCI, the rate of target vessel failure (TVF) defined as the composite of cardiac death, target vessel MI and ischemia-driven target vessel revascularization (ID-TVR) between PIOS and SOC.

6. Post-PCI FFR between the pressure microcatheter and pressure-wire guided strategies in patients undergoing PCI.

7. Post-PCI FFR between pressure PIOS and SOC strategies in patients undergoing PCI.

8. Post-PCI FFR in pressure PIOS-MC and PIOS-PW strategies in patients undergoing PCI.

9. The proportion of FFR > 0.90 between pressure microcatheter (MC) PIOS and SOC strategies in patients undergoing PCI.

10. The proportion of FFR > 0.80 in pressure PIOS and SOC strategies in patients undergoing PCI.

11. The proportion of FFR > 0.80 in pressure PIOS-MC and PIOS-PW strategies in patients undergoing PCI.

12. The proportion of FFR > 0.90 in pressure PIOS-MC and PIOS-PW strategies in patients undergoing PCI.

13. Rate of symptoms-free status assessed by the SAQ-7 between a pressure microcatheter and pressure-wire guided strategies at 12 months follow-up.

14. Rate of all-cause death in a pressure microcatheter and pressure-wire guided strategies.

15. Rate of myocardial infarction in a pressure microcatheter and pressure-wire guided strategies.

16. Rate of and unplanned revascularization in a pressure microcatheter and pressure-wire guided strategies.

17. In patients undergoing PCI, the rate of cardiac death between PIOS and SOC.

18. In patients undergoing PCI, the rate of target vessel MI between PIOS and SOC.

19. In patients undergoing PCI, the rate of ID-TVR between PIOS and SOC.

20. Rate of PCI-related MI (type 4a) between a pressure PIOS and SOC.

21. Rate of angiographic complications related to vessel wiring (i.e., Angiographic dissection >= NHLBI type B, perforations (Ellis classification), intra-procedural thrombotic events (including slow-flow, no-reflow, side branch closure, distal embolization, and intra-procedural stent thrombosis, as per the standard angiographic core laboratory definitions) in a pressure microcatheter and pressure-wire guided strategies.

22. Predictive capacity of the PPG derived from pressure microcatheter and pressure wire for post-PCI FFR.

23. Predictive capacity of the PPG derived from pressure microcatheter and pressure wire for TVF.

24. Predictive capacity of the PPG derived from pressure microcatheter and pressure wire for target-vessel MI.

25. Predictive capacity of the PPG derived from pressure microcatheter and pressure wire for ID-TVR.

26. Predictive capacity of the post-PCI residual pressure gradients from pressure microcatheter and pressure wire for target-vessel target vessel MI.

27. Predictive capacity of the post-PCI residual pressure gradients from pressure microcatheter and pressure wire for target vessel revascularization.

28. Rate of peri-procedural myocardial infarction stratified by PPG derived from pressure microcatheter and pressure wire.

29. Rate of peri-procedural myocardial injury stratified by PPG derived from pressure microcatheter and pressure wire.

30. Rate of Device Deficiencies and Adverse Events related to pressure

microcatheter and pressure wire.

Study description

Background summary

Invasive functional evaluation of coronary stenosis to decide upon revascularization has demonstrated clinical benefit in various clinical settings and in patients with different risk profiles. Today, guidelines recommend using resting or hyperemic pressure ratios to assess the hemodynamic significance of intermediate coronary lesions. Despite the evidence, physiology guided revascularization is applied only in a small proportion of patients undergoing PCI. There are several reasons, including the use of pressure wires of limited performance, which is particularly important when adopted in complex anatomic scenarios.

In addition to a distal FFR or non-hyperemic resting index value (NHPR), a pullback manoeuvre can be used to assess the distribution of epicardial resistance and characterize the pattern of coronary artery disease (CAD) as either focal or diffuse before PCI. After PCI, a pullback manoeuvre can help identify residual pressure gradients either inside or outside the stent that can be addressed by further post-dilatation of another PCI. Pullback manoeuvres help optimize PCI and achieve a higher degree of functional revascularization, which has been associated with improved clinical outcomes. However, with standard pressure wires, pullback manoeuvres lead to loss of wire position, further discouraging systematic adoption.

Recently, a new device for measuring physiological lesion severity, the pressure microcatheter, was introduced. The pressure microcatheter provides similar information to the conventional measurement technique but differs as it is easily advanced on a customary coronary wire and simplifies pullback maneuvers. The pressure microcatheter has been shown to provide comparable FFR results to pressure wires.
To date, there is a vast experience with the pressure microcatheter. Yet, the widespread applicability of pressure microcatheter in clinical practice will require studies investigating the equivalence of pressure wire-guided clinical decision making in terms of patient outcomes when used as a clinical decision making and optimization tool in patients considered or undergoing PCI.

To date, there is a vast experience with the pressure microcatheter. Yet, the widespread applicability of pressure microcatheter in clinical practice will require studies investigating the equivalence of pressure wire-guided clinical decision making in terms of patient outcomes when used as a clinical decision

making and optimization tool in patients considered or undergoing PCI.

Study objective

The primary objective of the study is to assess the safety and efficacy of a pressure microcatheter guided treatment decision and PCI optimization compared to a pressure wire based strategy.

Study design

The INSIGHTFUL-FFR study is an investigator-initiated, international, and multicenter trial of patients with stable coronary artery disease or stabilized non-ST elevation acute coronary syndrome (ACS) with epicardial stenosis considered for PCI aiming at comparing clinical outcomes between pressure microcatheter and pressure wire-guided strategies.

Following the identification of coronary stenosis, defined as at least one epicardial lesion between 30% to 90% diameter stenosis (%DS), patients will be randomized to either pressure microcatheter or pressure wire-based strategies for clinical decision making. Clinical decision making for PCI could be based either on FFR or NHPR. FFR or NHPR will support clinical decisions to defer or treat at the operator discretion. In cases with a positive FFR (<= 0.80) or NHPR (<=0.89), patients will undergo a hyperemic FFR pullback to guide the PCI procedure further. PCI will be performed using last-generation drug-eluting stents (DES) at operator*s discretion. After completing an angiographically successful PCI, patients will be randomized to FFR-guided stent optimization (PIOS) or standard of care (SOC).

The sites using an online platform will perform simple randomization (1:1:1:1 ratio) to either pressure microcatheter SOC, pressure wire SOC, pressure microcatheter PIOS or pressure wire PIOS. PCI treatment will be considered by the randomized methodology strategy, using the NHPR<=0.89 threshold, and FFR <=0.80. Subsequently, patients undergoing PCI will follow the pullback-based PCI optimization (PIOS) or SOC with either the pressure microcatheter or pressure wire. Patients randomized to any of the four groups in whom NHPR is >0.89 or FFR >0.80 PCI will be deferred and analyzed as such. The one-step randomization process in four groups permits an uninterrupted invasive procedure avoiding the logistic issues related to a second randomization during the invasive procedure while preserving the statistical power and balance between groups.

Study burden and risks

The potential risks for the patient are the known and common risks during the diagnostic work-up process or during invasive coronary angiography and PCI but are unrelated to this study. No additional risks for the patients participating in this study are expected. This study does not interfere with any common or

generally used test or processes.

The patients will not get a direct benefit by participating in this study. The results of this study could hopefully give benefit for future patients.

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

1. The subject must be at least 18 years of age and younger than 85 years old.
2. Eligible for elective PCI.
3. Stable angina or ACS (non-culprit vessels only and outside of primary intervention during acute STEMI)
4. Subject willing to participate and able to understand, read and sign the

Informed Consent.

Exclusion criteria

1. STEMI as clinical presentation.
2. Significant contraindication to adenosine administration (e.g. heart block, severe asthma)
3. Uncontrolled or recurrent ventricular tachycardia.
4. Hemodynamic instability.
5. Severe valvular disease.
6. Severe renal dysfunction, defined as an eGFR <=30 mL/min/1.73 m2.
7. Comorbidity with life expectancy <= 2 years.
8. Inability to take DAPT (both aspirin and a P2Y12 inhibitor) for at least 12 months in the patient presenting with an ACS, or at least 6 months in the patient presenting with stable CAD, unless the patient is also taking chronic oral anticoagulation in which case a shorter duration of DAPT may be prescribed per local standard of care.
9. Planned major cardiac or non-cardiac surgery within 24 months after the index procedure.

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-02-2024
Enrollment:	140

Type:	Actual

Medical products/devices used

Generic name:	TruePhysio Rapid Exchange Pressure Microcatheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-12-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT05437900
CCMO	NL82417.091.22