Radiographic imaging Validation and EvALuation for Angio iFR (ReVEAL iFR)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON49764

Source
ToetsingOnline

Brief title
ReVEAL iFR

Condition

- Coronary artery disorders

Synonym
coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: bedrijf

Intervention

Keyword: coronary artery lesion, evaluation, Philips Angio-iFR medical software device, validation

Outcome measures

Primary outcome

Diagnostic accuracy of the image-derived iFR and FFR estimate for a given

lesion compared to the corresponding invasive iFR and FFR yields a sensitivity

* 75% and specificity * 80%

Secondary outcome

* Diagnostic agreement between the angiographic derived iFR/FFR estimate and

the reference invasive measure for the same lesion is within the inherent

measurement variability

* Superior specificity of the iFR/FFR estimate over visual determination of

stenosis severity based on the angiogram alone (i.e., *50% diameter stenosis)

* Inter- and intra-observer diagnostic and measurement agreement between

repeated estimates made by the medical software device for a given lesion

* Diagnostic agreement measures:

* Diagnostic accuracy

* Positive (PPV) and negative predictive values (NPV)

* Area under the Received Operating Characteristics (ROC) curve (AUC)

* Positive and negative likelihood ratios

* Diagnostic odds ratio

Study description

Background summary

The Philips Angio-iFR medical software device is intended to provide information on the functional significance of a coronary artery lesion to provide guidance on diagnostic decisions similar to that obtained through invasive measures of iFR and FFR. The software application uses the vessel geometry obtained from a coronary angiographic image together with a lumped parameter physiological model to provide the associated iFR and FFR estimates.

Study objective

This study is intended to demonstrate the diagnostic performance of the image-derived physiology model using the invasive physiological measures as the reference standard.
Specific objectives include the following:
i) Demonstrate the sensitivity and specificity of image-derived iFR and FFR results for identifying functionally significant lesions as determined by the corresponding invasive measures;
ii) Demonstrate the diagnostic agreement of image-derived iFR and FFR estimates with the corresponding invasive measures;
iii) Demonstrate the diagnostic performance of image derived physiology estimate (iFR/FFR) is superior to visual angiographic assessment for the identification of functionally significant stenoses as determined by the corresponding invasive physiology measures;
iv) Demonstrate reproducibility of the image-derived estimate for a given operator and across multiple operators for a given lesion.

Study design

Multi-center, prospective, single-arm, open-label, data collection with centralized off-line data analysis

Study burden and risks

In addition to the minimal risks, as described in E9, there is no impact on the patient or his treatment in this observational diagnostic study. The knowledge obtained through this study can ensure a less invasive diagnosis in the future.

Contacts

Public

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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. *18 years old
2. At least 1 de-novo lesion in 1 or more major epicardial vessels of 40-90% angiographic stenosis with a reference vessel size *2.5mm in the diseased segment by visual estimate
3. Able and willing to provide informed consent

Exclusion criteria

1. Presenting with an acute coronary syndrome (ACS), or documented ACS within 4 weeks prior to the scheduled index procedure
2. Cardiogenic shock (sustained (>10 min) systolic blood pressure <90 mmHg in absence of inotropic support or the presence of an intra-aortic balloon pump)
3. Presence of cardiac arrhythmias (e.g., atrial fibrillation, AV-block)
4. Prior cardiac surgery or implant, including CABG, heart transplant, surgical heart valve replacement or repair, TAVI/TAVR, presence of an ICD or pacemaker

5. Target vessel supplied by a left main coronary artery demonstrating any disease present (isolated or non-isolated)
6. Target vessel supplied by right coronary artery demonstrating any ostial disease (located immediately at the origin of the coronary vessels from the aorta)
7. Target vessel with Chronic Total Occlusion (CTO) in the ipsilateral territory or target vessel with an untreated CTO in the contralateral territory. Note: if a CTO existing in the contralateral territory is successfully opened, the target vessel in the contralateral territory can be included following CTO treatment.
8. Target vessel with severe tortuosity (*1 bends of 90° or more, or *3 or more bends of 45°- 90° proximal to the diseased segment)
9. Target vessel with heavy calcification (multiple persisting opacifications of the coronary wall visible in more than one projection surrounding the complete lumen of the coronary artery at the site of the lesion.)
10. Target vessel with TIMI flow grade 1 or 0
11. Target vessel with severe diffuse disease (more than 75% of the length of the segment having a vessel diameter of 2mm, irrespective of the presence or absence of a lesion)
12. Target lesion is at a bifurcation/trifurcation
13. Target arteries supplying akinetic or severely hypokinetic territories if already known based on prior imaging
14. Target vessel is supplied by major collaterals
15. Target stenosis associated with myocardial bridge
16. Any vascular abnormality precluding optimal contrast opacification (e,g, thrombus, ulceration)
17. Severe aortic or mitral valve disease
18. Known ejection fraction *30%
19. Known severe renal insufficiency (eGFR<30ml/min/1.72m2)
20. Any fluoroscopic interference that renders the wire position unclear
21. Contraindication for adenosine or other hyperemic agent (e.g., caffeine ingestion *18 hours, COPD, hypotension, AV block)
22. Known pregnancy or planning to become pregnant
23. Participating in another interventional investigational study that may acutely impact microvascular function at the time of the physiology procedure

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2020
Enrollment:	108
Type:	Actual

Medical products/devices used

Generic name:	Angio iFR
Registration:	No

Ethics review

Approved WMO Date:	15-07-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	22-06-2020
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
Other	03857503
CCMO	NL69439.099.19