

ClinicalTrials.gov PRS **DRAFT Receipt (Working Version)**
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ClinicalTrials.gov ID: NCT02493634

Study Identification

Unique Protocol ID: N4IPMCF2015

Brief Title: Post-market Clinical Follow-up Study With Magnetic Resonance Imaging Conditional Guide Wire (MRWIREPMCF)

Official Title: Post-market Clinical Follow-up Study With Magnetic Resonance Imaging Conditional Guide Wire

Secondary IDs:

Study Status

Record Verification: February 2016

Overall Status: Recruiting

Study Start: August 2015

Primary Completion: June 2016 [Anticipated]

Study Completion: August 2016 [Anticipated]

Sponsor/Collaborators

Sponsor: Nano4Imaging GmbH

Responsible Party: Sponsor

Collaborators: CERES GmbH

Oversight

FDA Regulated?: No

IND/IDE Protocol?: No

Review Board: Approval Status: Approved

Approval Number: 254/14

Board Name: Ethikkommission, Medical Faculty

Board Affiliation: Technical University Munich

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Data Monitoring?: No

Plan to Share Data?: Undecided

Oversight Authorities: Germany: Ethics Commission

Study Description

Brief Summary: This is post-market clinical follow-up study on 25 consecutive patients in two centers to evaluate the safety and performance of magnetic resonance imaging conditional guide wire and the acceptability of identified risks in the clinical evaluation and to detect emerging risks on the basis of factorial evidence. The procedure will be done in patients with a clinical indication for cardiac magnetic resonance and conventional catheterisation.

Detailed Description: This is post-market clinical follow-up study on 25 consecutive patients in two centers to evaluate the safety of a guide wire conditional for use in magnetic resonance imaging and the acceptability of identified risks in the clinical evaluation and to detect emerging risks on the basis of factorial evidence.

The guidewire is used to access the patients central circulatory system and in particular for the introduction and exact placement of a pressure catheter to measure the pressure gradient over the aortic arch. The procedure will be done in patients with a clinical indication for cardiac magnetic resonance and conventional catheterisation. Patients need to have a body weight over 40 kg and the introduction of a 5 French catheter should be possible. The primary endpoint is the measurement of procedural success, defined as successful insertion, steerability and visibility in MRI, in the absence of device related adverse events such as damage to vessel wall. In addition structural integrity of the instruments is to be assessed.

Conditions

Conditions: Congenital Heart Defect

Keywords: Magnetic Resonance spectroscopy
Aortic Arch

Study Design

Study Type: Interventional

Primary Purpose: Diagnostic

Study Phase: N/A

Intervention Model: Single Group Assignment

Number of Arms: 1

Masking: Single Blind (Outcomes Assessor)

Allocation: N/A

Endpoint Classification: Safety/Efficacy Study

Enrollment: 25 [Anticipated]

⚠ WARNING : Masking 'Single Blind' implies that this is a multi-arm study, but only one arm has been specified.

Arms and Interventions

Arms	Assigned Interventions
pressure gradient measurement Diagnostic procedure to measure pressure gradient in series of patients. Focus is on safety and absence of adverse events	Procedure/Surgery: pressure gradient measurement A guidewire is used to introduce and position a pressure catheter under magnetic resonance

Arms	Assigned Interventions
	<p>guidance to conduct flow and pressure measurement in the aortic arch to evaluate vascular resistance.</p> <p>Other Names:</p> <ul style="list-style-type: none"> • MRWire <p>Device: MRWire</p>

NOTE : Intervention Description: data not entered.

NOTE : Intervention 'MRWire' has not been included in any Arm/Group Descriptions.

Outcome Measures

Primary Outcome Measure:

1. Procedural success

[Time Frame: Up to 30 days after procedure] [Safety Issue: Yes]

procedural success means that insertion, steerability and visibility of the guide wire in the MR guided intervention was successfully reached, in the absence of adverse events up to 30 days after procedure

Eligibility

Minimum Age:

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- patients with clinical indication for cardiac magnetic resonance and conventional diagnostic catheterisation
- patients with body weight of > 40 kg in which the introduction of an introducer of > 5 French is possible.
- subject provided written informed consent using the approved consent form or in case of a minor the subject provided written assent and its legal guardian provided written informed consent.

Exclusion Criteria:

- major surgery in the last 42 days
- history of irreversible bleeding disorder
- contraindication to cardiac magnetic resonance
- Contraindications to guidewire procedures, such as evidence of active infection
- women of child-bearing potential who cannot provide a negative pregnancy test
- chronic total occlusion.

Contacts/Locations

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References

Citations: Kos S, Huegli R, Hofmann E, Quick HH, Kuehl H, Aker S, Kaiser GM, Borm PJ, Jacob AL, Bilecen D. First magnetic resonance imaging-guided aortic stenting and cava filter placement using a polyetheretherketone-based magnetic resonance imaging-compatible guidewire in swine: proof of concept. *Cardiovasc Intervent Radiol*. 2009 May;32(3):514-21. doi: 10.1007/s00270-008-9483-5. Epub 2008 Dec 30. PubMed 19115070

Kos S, Huegli R, Hofmann E, Quick HH, Kuehl H, Aker S, Kaiser GM, Borm PJ, Jacob AL, Bilecen D. MR-compatible polyetheretherketone-based guide wire assisting MR-guided stenting of iliac and supraaortic arteries in swine: feasibility study. *Minim Invasive Ther Allied Technol*. 2009;18(3):181-8. doi: 10.1080/13645700902921971. PubMed 19431070

Kos S, Huegli R, Hofmann E, Quick HH, Kuehl H, Aker S, Kaiser GM, Borm PJ, Jacob AL, Bilecen D. Feasibility of real-time magnetic resonance-guided angioplasty and stenting of renal arteries in vitro and in Swine, using a new polyetheretherketone-based magnetic resonance-compatible guidewire. *Invest Radiol*. 2009 Apr;44(4):234-41. doi: 10.1097/RLI.0b013e31819b00f1. PubMed 19252440

Links:

Study Data/Documents: