Protocol Registration Receipt
02/04/2009

Novel Angioplasty Using Coronary Accessor (NAUSICA)

This study is currently recruiting participants.
Verified by Nausica, February 2009

Sponsored by:	Nausica NPO International TRI Network
Information provided by:	Nausica
ClinicalTrials.gov Identifier:	NCT00815997

Purpose

To investigate the advantage of using a 4Fr guiding catheter over a 6 Fr, frequencies of radial artery occlusion after transradial coronary intervention (TRI) will be evaluated. Radial artery occlusion rate in 4 Fr TRI group is expected to be not more than that in 6Fr groups.

Condition	Intervention	Phase
Radial Artery Occlusion	Device: TRI using a 4-Fr guiding catheter	N/A

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, N/A, Efficacy Study
Official Title: Novel Angioplasty USIng Coronary Accessor

Further study details as provided by Nausica:

Primary Outcome Measure:

- pulsation of the radial artery [Time Frame: within 2 days after TRI] [Designated as safety issue: No]

Secondary Outcome Measures:

- success of TRI [Time Frame: within 2 days after TRI] [Designated as safety issue: Yes]

Estimated Enrollment: 160
Study Start Date: January 2009
Estimated Study Completion Date: December 2009
Estimated Primary Completion Date: December 2009

Arms	Assigned Interventions
No Intervention: 6 Fr TRI TRI will be performed using a 6-Fr guiding catheter.	
Active Comparator: 4-Fr TRI TRI will be performed using a 4-Fr guiding catheter.	Device: TRI using a 4-Fr guiding catheter TRI will be performed using a 4-Fr guiding catheter.

Prerequisites for TRI were a sufficiently pulsating radial artery and presence of an ulnar pulse with a sufficient palmar arch, as evidenced by the absence of digital ischemia according to the Allen's test. Exclusion criteria for the current study included planned use of a cutting balloon, rotational atherectomy, directional coronary atherectomy, and intravascular ultrasound, which were not compatible with 4-Fr catheter.

Patency of the radial artery after TRI will be evaluated by pulsation of the radial artery, and frequencies of which will be compared between those receiving 4Fr vs 6 Fr coronary interventions.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both

Inclusion Criteria:

- Prerequisites for transradial intervention were a sufficiently pulsating radial artery and presence of an ulnar pulse with a sufficient palmar arch, as evidenced by the absence of digital ischemia according to the Allen's test.

Exclusion Criteria:

- Exclusion criteria included planned use of a cutting balloon, rotational atherectomy, directional coronary atherectomy, and intravascular ultrasound, which were not compatible with 4-Fr catheter.

Contacts and Locations

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More Information

Responsible Party: Shonan Kamakura General Hospital (Shigeru Saito)
Study ID Numbers: 2008-28
Health Authority: Japan: Institutional Review Board