RAP and BEAT Clinical Trial (Radial Artery Patency and Bleeding, Effectiveness, Adverse evenT Trial)

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The objective of this study is to demonstrate the safety and efficacy of thenew 6Fr sheath (Glidesheath slender 6Fr; GSS 6Fr) compared with thecontemporary 5Fr sheath (standard of care 5Fr; SOC 5Fr) both from Terumo;Tokyo, Japan.

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

Summary

ID

NL-OMON42483

Source
ToetsingOnline

Brief title
RAP and BEAT

Condition

- Coronary artery disorders

Synonym
radial artery occlusion occlusie van de a. radialis

Research involving
Human

Sponsors and support

Primary sponsor: NPO International TRI Network, Research Center, Cardiovascular Dept., Shonan Kamakura General hospital
Source(s) of monetary or material Support: Terumo

Intervention

Keyword: coronary artery angiography, percutaneous coronary intervention, radial artery occlusion

Outcome measures

Primary outcome

The primary endpoint is composite of the freedom from radial artery occlusion

(RAO) and local bleeding from the puncture site at the time of discharge or

the next day, the earlier of the two.

Secondary outcome

Procedure success rate at the index procedure.

* Vascular access site complication

* Radial spasm during the index procedure.

* Total Procedure Time

* Total Amount of Contrast Dye

* Fluoroscope time

* Procedure failure due to the assigned sheath.

* Pain score

Study description

Background summary

Radial artery puncture and sheath insertion can induce acute injuries and chronic
thickening of the radial artery intima, which may subsequently result in the radial artery occlusion (RAO)
with or without thrombus formation. TERUMO corporation developed a new 6Fr sheath (Glidesheath slender 6Fr: GSS
6Fr). It has the same inner lumen diameter as the contemporary 6Fr sheath but

the sheath outer
The Study Protocol of RAP and BEAT Clinical Trial
Confidential Document written by Shigeru SAITO, MD 9
Radifocus Introducer *H 6Fr
(Glidesheath) Glidesheath Slender 6Fr
diameter is similar to the contemporary 5Fr sheath. With the introduction of this new sheath into
transradial coronary procedures, it is reasonably expected that PCI through TRI can be
performed in the majority of real-world clinical situations without significant limitations, while
reducing RAO by the use of smaller outer caliber sheath compared with the use of contemporary
6Fr sheath.
A recent preliminary study by Amit Aminian reported that the Glidesheath Slender 6Fr was safe
and feasible with a high rate of procedural success and a low rate of RAO

Study objective

The objective of this study is to demonstrate the safety and efficacy of the new 6Fr sheath (Glidesheath slender 6Fr; GSS 6Fr) compared with the contemporary 5Fr sheath (standard of care 5Fr; SOC 5Fr) both from Terumo; Tokyo, Japan.

Study design

Investigators-initiated Randomized, prospective, controlled, open-labeled, multicenter Clinical Trial (RCT):
Approximately 1,900 patients who undergo diagnostic coronary artery angiography or subsequent percutaneous coronary intervention (PCI) via transradial approach using any one of 4, 5, or 6Fr diagnostic catheters or either 5 or 6Fr guiding catheters for subsequent PCI will be enrolled. Patients are randomized 1:1 to receive GSS 6Fr sheath (950 patients) and SOC 5Fr sheath (950 patients). The two patient groups will then be immediately randomized again to 475 patients for Patent hemostasis with TR band (Terumo co.) and 475 patients for any hemostasis procedure customarily done as a standard practice in the hospital. The enrollment will be finished when the number of patients who undergo coronary artery angiography reaches 1,900 patients.

Intervention

receive GSS 6Fr sheath (950 patients) or SOC 5Fr
sheath (950 patients).

Study burden and risks

n/a

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

5.4 General Inclusion Criteria
1. Patient must be at least 18 years of age.
2. Patient is able to verbally acknowledge an understanding of the associated risks, benefits and treatment alternatives

3. Patient who is expected to diagnose by coronary artery angiography or followed by PCI.
4. Patient must agree to undergo all protocol-required follow-up examinations.
5. Patient who can accept radial access.

Exclusion criteria

1. Patient has other medical illness (e.g., cancer or congestive heart failure) that may cause non-compliance with the protocol, confound the data interpretation or is associated with a limited life expectancy (i.e., less than one year).
2. Hemodialysis patient
3. STEMI

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2016
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	14-01-2016

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL53530.029.15