

Nobori 2 study to confirm the efficacy and safety of the CE marked Nobori stent in routine use

Submission date 08/05/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 05/06/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/02/2017	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Danny Detiege

Contact details
Research Park Zone 2 Haasrode
Interleuvenlaan 40
Leuven
Belgium
B-3001
+32 (0)16 38 13 80
danny.detiege@terumo-europe.com

Additional identifiers

Protocol serial number
T109E2

Study information

Scientific Title

NOBORI 2: a prospective, multi-centre, observational study of the Nobori™ drug eluting stent system

Acronym

NOBORI 2

Study objectives

Primary objective:

To validate, in a real life setting, the safety and effectiveness of the Nobori™ drug eluting stent (DES) system previously observed in randomised trials.

Secondary objectives:

1. To assess the long term safety of the Nobori™ stent in a fully representative patient population
2. To assess the performance of the Nobori™ stent in various patient/lesion subpopulations
3. To identify rationale for further randomised studies in specific subsets
4. To assess the possible benefit of bioresorbable polymer on long term safety

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Freiburger ethik kommission (Germany), 17/03/2008
2. Ziekenhuis Oost Limburg and Onze Lieve Voruw Ziekenhuis Aalst (Belgium), 29/04/2008
3. Bad Oeynhausen (Germany), 28/04/2008

All other participating countries have submitted in April through June to all participating hospital Ethics Committees wherever such requirement exists prior to enrolment of patients. Last site start up expected July 2008.

Primary study design

Observational

Study design

Observational single-arm prospective multi-centre study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atheromatous coronary artery disease

Interventions

Observational collection of routine hospital practice, clinical follow-up for monitoring of adverse and major cardiac events (death, infarction, re-interventions on target lesion, stent thrombosis), documentation of cardiac medication regimen, laboratory results if performed in routine practice. Follow up at 1, 6 and 12 months, and yearly up to 5 years.

Intervention Type

Device

Primary outcome(s)

Device oriented composite endpoint, defined as cardiac death, myocardial infarction (Q-wave and non-Q-wave not clearly attributable to non-target vessel) and clinically driven target lesion revascularisation at 12 months post-procedure.

Key secondary outcome(s)

1. Device oriented composite endpoint, defined as cardiac death, myocardial infarction (MI) (Q-wave and non-Q-wave not clearly attributable to non-target vessel) and clinically driven target lesion revascularisation at 1 and 6 months, 2, 3, 4 and 5 years post-procedure
2. Patient oriented composite endpoint defined as any cause mortality, MI (Q wave and non-Q wave), or any clinically driven target vessel revascularisation at 1, 6 and 12 months and at 2, 3, 4 and 5 years
3. Death and MI at 1, 6 and 12 months, 2, 3, 4 and 5 years
4. Death and post-procedural MI at 1, 6 and 12 months, 2, 3, 4 and 5 years
5. Stent thrombosis (definite and probable according to Academic Research Consortium [ARC] definitions) at 1, 6 and 12 months, 2, 3, 4 and 5 years
6. Primary stent thrombosis (definite and probable according to ARC definitions) at 1, 6 and 12 months, 2, 3, 4 and 5 years
7. Secondary stent thrombosis (definite and probable according to ARC definitions) at 1, 6 and 12 months, 2, 3, 4 and 5 years
8. Duration of dual antiplatelet therapy
9. Death, post-procedural MI and stent thrombosis rate during the course of dual antiplatelet therapy versus the same events after cessation of dual antiplatelet therapy
10. Clinically driven target lesion revascularisation (TLR) at 1, 6 and 12 months, 2, 3, 4 and 5 years
11. Clinically driven target vessel revascularisation (TVR) at 1, 6 and 12 months, 2, 3, 4 and 5 years
12. Total revascularisation rate (clinically and non clinically driven) at 1, 6 and 12 months, 2, 3, 4 and 5 years
13. Device success defined as the attainment of less than 30% residual stenosis by visual assessment using the Nobori™ stent only
14. Lesion success defined as the attainment of less than 30% residual stenosis by visual assessment using any percutaneous method
15. Procedure success defined as achievement of a final diameter stenosis of less than 30% by visual assessment using any percutaneous method, without the occurrence of death, Q wave or non-Q wave MI, or repeat revascularisation of the target lesion during the hospital stay

All above mentioned endpoints in specific subgroups enrolling sufficient number of patients.

Completion date

30/11/2013

Eligibility

Key inclusion criteria

1. Patient is at least 18 years old, either sex
2. The patient is, according to hospital routine practice, eligible for percutaneous coronary intervention using DES (and reference vessel diameter [RVD] matches available Nobori™ DES sizes)
3. Patient or the patients legal representative has been informed of the nature of the study and

agrees to its provisions and has provided written informed consent as approved by the Institutional Review Board/Ethics Committee of the respective clinical site, wherever such requirement exists

NOTE: In order to avoid bias it is recommended that all investigators aim to enrol all patients complying with inclusion criteria. It is also desirable to have at least two cardiologists as investigators in each centre.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Exclusion criteria will be according to the instructions for the use of the device.

Date of first enrolment

01/04/2008

Date of final enrolment

30/11/2013

Locations**Countries of recruitment**

United Kingdom

Belgium

Czech Republic

Denmark

Finland

France

Germany

Greece

Hungary

Indonesia

Israel

Italy

Korea, South

Latvia

Macao

Malaysia

Morocco

Netherlands

New Zealand

Russian Federation

Serbia

Singapore

Slovenia

Sweden

Switzerland

Tunisia

Türkiye

Viet Nam

Study participating centre
Research Park Zone 2 Haasrode
Leuven
Belgium
B-3001

Sponsor information

Organisation

Terumo Europe N.V. (Belgium)

ROR

<https://ror.org/043vk3t22>

Funder(s)**Funder type**

Industry

Funder Name

Terumo Europe N.V. (Belgium) (ref: T109E2)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/05/2012		Yes	No
Results article	results	10/02/2017		Yes	No