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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/06/2008	**Overall study status** Completed	
Last Edited 13/02/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

Study design
Observational single-arm prospective multi-centre study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/04/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
3000

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

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

United Kingdom

Viet Nam

Study participating centre
Research Park Zone 2 Haasrode
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Sponsor information

Organisation
Terumo Europe N.V. (Belgium)

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Sponsor type
Industry

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https://ror.org/043vk3t22

Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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