XIENCE 28 Global Study

Published: 29-03-2018
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The primary objective of this trial is to further evaluate safety of 1-month (as short as 28 days) dual antiplatelet therapy (DAPT) in subjects at high risk of bleeding (HBR) undergoing percutaneous coronary intervention (PCI) with XIENCE.

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

Summary

ID

NL-OMON48553

Source
ToetsingOnline

Brief title
XIENCE 28

Condition

- Coronary artery disorders

Synonym
Acute coronary syndrome, heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: DAPT Double anti platelet therapy, Percutaneous coronary interventention, Xience stent

Outcome measures

Primary outcome

Net Adverse Clinical Endpoint (NACE, a composite rate of all-cause death, all myocardial infarction (modified Academic Research Consortium [ARC]), stent thrombosis (ARC definite or probable), stroke or major bleeding (Bleeding defined by the Bleeding Academic Research Consortium [BARC] type 2-5) from 1 to 6 months

Secondary outcome

The following endpoints will be assessed from 1 to 6 months:

* Stent thrombosis (ARC definite/probable, ARC definite)

* All death, cardiac death, vascular death, non-cardiovascular

* All myocardial infarction (MI) and MI attributed to target vessel (TV-MI, modified ARC)

* Composite of cardiac death or MI (modified ARC)

* Composite of all death or all MI (modified ARC)

* All stroke, ischemic stroke and hemorrhagic stroke

* Clinically-indicated target lesion revascularization (CI-TLR)

* Clinically-indicated target vessel revascularization (CI-TVR)

* Target lesion failure (TLF, composite of cardiac death, TV-MI and CI-TLR)

* Target vessel failure (TVF, composite of cardiac death, TV-MI and CI-TVR)

* Bleeding defined by the Bleeding Academic Research Consortium (BARC) type 2-5

The primary endpoint of NACE and all the above secondary endpoints will also be

assessed from 6 months to 12 months and from 1 month to 12 months,

respectively.

Study description

Background summary

Long-term dual antiplatelet therapy (DAPT) is known to increase the risk of bleeding. High Bleeding Risk (HBR) patients represent approximately 15% or more of the current percutaneous coronary intervention (PCI) population. The optimal duration of DAPT for HBR subjects shall be better addressed. For some HBR patients, prolonging DAPT even beyond one month may be detrimental and hazardous. Given the lack of specific data in this arena for DES, the current ACC/AHA guidelines recommend use of bare metal stent (BMS) with 1-month DAPT. While this strategy aims to minimize the risk of bleeding in such patients, the use of BMS poses a higher risk of restenosis and re-intervention. Therefore, stenting with a DES followed by a shortened course of DAPT may represent a more favorable treatment option if there is no significant increase in ischemic events.

XIENCE has consistently been shown to have the best safety profile among the coronary stents, even when compared to BMS and biodegradable polymer DES. The benefit/risk ratio of 1-month DAPT following XIENCE implantation in this population has not been specifically addressed. The XIENCE 28 Global Study will evaluate this important clinical question in a carefully controlled study setting. The results of the trial could potentially provide a definitive answer for the physicians as to the treatment of HBR patients with a safe and effective DES option.

Study objective

The primary objective of this trial is to further evaluate safety of 1-month (as short as 28 days) dual antiplatelet therapy (DAPT) in subjects at high risk of bleeding (HBR) undergoing percutaneous coronary intervention (PCI) with XIENCE.

Study design

prospective, single arm, multi-center, open label trial

Study burden and risks

Due to the short DABT period of 1 months there is a possibility that the

participants have a higher risk of stent thrombosis. This will be evaluated in the trial.
The shortened DABT period will decrease the bleeding risk in the study population.

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

1. Subject is considered at high risk for bleeding (HBR), defined as meeting one or more of the following criteria at the time of registration and in the opinion of the referring physician, the risk of major bleeding with > 1-month DAPT outweighs the benefit:
a) * 75 years of age.
b) Clinical indication for chronic or lifelong anticoagulation therapy.
c) History of major bleeding which required medical attention within 12 months of the index

procedure.
d) History of stroke (ischemic or hemorrhagic).
e) Renal insufficiency (creatinine * 2.0 mg/dl) or failure (dialysis dependent).
f) Systemic conditions associated with an increased bleeding risk (e.g. hematological disorders, including a history of or current thrombocytopenia defined as a platelet count <100,000/mm3, or any known coagulation disorder associated with increased bleeding risk).
g) Anemia with hemoglobin < 11g/dl.
2. Subject must be at least 18 years of age.
3. Subject or a legally authorized representative must provide written informed consent as approved by the Ethics Committee (EC) of the respective clinical site prior to any trial related procedure.
4. Subject is willing to comply with all protocol requirements, including agreement to stop taking P2Y12 inhibitor at 1 month, if eligible per protocol.
5. Subject must agree not to participate in any other clinical trial for a period of one year following the index procedure.
Angiographic Inclusion Criteria
1. Up to three target lesions with a maximum of two target lesions per epicardial vessel.
Note:
* The definition of epicardial vessels means left anterior descending coronary artery (LAD), left circumflex coronary artery (LCX) and right coronary artery (RCA) and their branches. For example, the subject must not have >2 lesions requiring treatment within both the LAD and a diagonal branch in total.
* If there are two target lesions within the same epicardial vessel, the two target lesions must be at least 15 mm apart per visual estimation; otherwise this is considered as a single target lesion.
2. Target lesion * 32 mm in length by visual estimation.
3. Target lesion must be located in a native coronary artery with visually estimated reference vessel diameter between 2.25 mm and 4.25 mm.
4. Exclusive use of XIENCE family of stent systems during the index procedure.
5. Target lesion has been treated successfully, which is defined as achievement of a final in-stent residual diameter stenosis of <20% with final TIMI-3 flow assessed by online quantitative angiography or visual estimation, with no residual dissection NHLBI grade * type B, and no transient or sustained angiographic complications (e.g., distal embolization, side branch closure), no chest pain lasting > 5 minutes, and no ST segment elevation or depression lasting > 5 minutes.

Exclusion criteria

1. Subject with an indication for the index procedure of acute ST-segment elevation MI (STEMI) or non ST-segment elevation MI (NSTEMI), defined as acute ischemic symptoms occurring within 72 hours before index procedure AND either ST-segment deviation of 1 mm or more or elevated levels of a cardiac biomarker of necrosis (CK-MB or troponin T or I greater than the upper limit of normal; If CK-MB or troponin is not available, total CK > 2 times upper limit of normal).
2. Subject has a known hypersensitivity or contraindication to aspirin, heparin/bivalirudin,

P2Y12 inhibitors (clopidogrel/prasugrel/ticagrelor), everolimus, cobalt, chromium, nickel, tungsten, acrylic and fluoro polymers or contrast sensitivity that cannot be adequately pre-medicated.
3. Subject with implantation of another drug-eluting stent (other than XIENCE) within 12 months prior to index procedure.
4. Subject has a known left ventricular ejection fraction (LVEF) <30%.
5. Subject judged by physician as inappropriate for discontinuation from P2Y12 inhibitor use at 1 month, due to another condition requiring chronic P2Y12 inhibitor use.
6. Subject with planned surgery or procedure necessitating discontinuation of P2Y12 inhibitor within 1 month following index procedure.
7. Subject with a current medical condition with a life expectancy of less than 12 months.
8. Subject intends to participate in an investigational drug or device trial within 12 months following the index procedure.
9. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year following index procedure. Female subjects of child-bearing potential must have a negative pregnancy test done within 7 days prior to the index procedure per site standard test.
Note: Female subjects of childbearing potential should be instructed to use safe contraception (e.g., intrauterine devices, hormonal contraceptives: contraceptive pills, implants, transdermal patches hormonal vaginal devices, injections with prolonged release.) It is accepted, in certain cases, to include subjects having a sterilised regular partner or subjects using a double barrier contraceptive method. However, this should be explicitly justified in special circumstances arising from the trial design, product characteristics and/or trial population
10. Subject is part of a vulnerable population, defined as subject whose willingness to volunteer in a clinical investigation could be unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples of populations which may contain vulnerable subjects include: individuals with lack of or loss of autonomy due to immaturity or through mental disability,
persons in nursing homes, children, impoverished persons, subjects in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, and those incapable of giving informed consent. Other vulnerable subjects include, for example, members of a group with a hierarchical structure such as university students, subordinate hospital and laboratory personnel, employees of the sponsor, members of the armed forces, and persons kept in detention.
11. Subject is currently participating in another clinical trial that has not yet completed its primary endpoint.

Angiographic Exclusion Criteria
1. Target lesion is in a left main location.
2. Target lesion is located within an arterial or saphenous vein graft.
3. Target lesion is restenotic from a previous stent implantation.
4. Target lesion is a total occluded lesion (TIMI flow 0).
5. Target lesion contains thrombus as indicated in the angiographic images.
6. Target lesion is implanted with overlapping stents, whether planned or for bailout.
7. Subjects who had additional clinically significant lesion (s) in target or non-target vessel for which PCI may be required within 12 months after the index procedure. (Note: planned

staged procedures are allowed (recommend to be performed within 30 days) and with XIENCE stents only. The last staged procedure is considered as the index procedure.)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-05-2018
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2018
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO Date:	24-04-2018
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO Date:	19-07-2018
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO Date:	12-02-2019
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
ClinicalTrials.gov	NCT03355742
CCMO	NL63457.099.17