Trial Description

Title

Pharmacodynamic comparison of thienopyridine loading strategies in patients undergoing elective coronary stenting

Trial Acronym

ExcelsiorLOAD

URL of the trial

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Brief Summary in Lay Language

**Patients undergoing implantation of a coronary stent need a sufficient inhibition of their platelets to prevent complications such as the abrupt occlusion of the coronary vessel.
Since in most patients it is unknown before the examination if a coronary stent is needed, medications that can achieve a sufficient inhibition of the platelets can often only be provided immediately before placement of the coronary stent according to current guidelines. This can lead to suboptimal inhibition of the platelets at time of intervention.**

This study aims to identify effective pre-treatment strategies that can achieve a sufficient peri-interventional platelet inhibition at time of intervention. The tested pretreatment strategies are Clopidogrel 600mg, Prasugrel 30mg and, Prasugrel 60mg.

Brief Summary in Scientific Language

**Patients undergoing elective percutaneous coronary intervention (PCI) need a sufficient antiplatelet effect for prevention of ischemic complications.
According to current guidelines, elective patients should be pretreated with clopidogrel before PCI (loading dose at least 2 hours before PCI). However, guidelines also recommend not pretreating patients with clopidogrel when coronary anatomy is not known since some patients without indication for PCI would also receive clopidogrel and get therefore exposed to an unnecessary bleeding risk. Thus, these recommendations would prevent PCI immediately after diagnostic angiography, which is clinical routine in many hospitals.
This trial aims to identify effective loading strategies that can be given immediately before PCI and that achieve a sufficient peri-interventional platelet inhibition. The tested pretreatment strategies are Clopidogrel 600mg, Prasugrel 30mg and, Prasugrel 60mg.**

Organizational Data

- DRKS-ID: **DRKS00006102**

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- Date of Registration in DRKS: **2014/05/21**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **188/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2014-001148-40**

Health condition or Problem studied

- ICD10: **I25 - Chronic ischaemic heart disease**

Interventions/Observational Groups

- Arm 1: **Efient (Prasugrel), 60mg oral loading dose, (tablet), single dose**
- Arm 2: **Efient (Prasugrel), 30mg oral loading dose, (tablet), single dose**
- Arm 3: **Plavix (Clopidogrel), 600mg oral loading dose, (tablet), single dose**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **IIIb**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

Proportion of patients with ADP-induced platelet aggregation < 468 AU x min tested 1 hour following loading dose

Secondary Outcome

Absolute ADP-induced platelet aggregation tested 0.5, 1.0, 1.5, 2.0, and 3.0 hours and day 1 following loading dose
Proportion of patients with ADP-induced platelet aggregation < 468 AU x min tested 2, 3 hours and day 1 following loading dose
Proportion of patients with ADP-induced platelet aggregation > 188 and < 468 AU x min tested 1, 2, 3 hours and day 1 following loading dose
Ischemic and bleeding events within 4 weeks after inclusion (death, myocardial infarction, revascularization, stroke, bleeding according to BARC Criteria).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Universitäts-Herzzentrum Freiburg - Bad Krozingen, Bad Krozingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/06/11**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Stable patients with obstructive coronary heart disease and planned coronary stent implantation.
Pretreatment with aspirin (100mg daily or loading dose of 400mg before coronary angiography).

Age >= 18 years.
Written informed consent.

Exclusion criteria

Acute myocardial infarction
Treatment with ticagrelor, prasugrel, fibrinolysis, or GP IIb/IIIa inhibitor within 7 days before enrollment.
Contraindication for treatment with aspirin, clopidogrel, or prasugrel (in particular: active bleeding, history of stroke or TIA).
Current oral anticoagulation.
Severe thrombocytopenia (< 50.000/µl).
Known severe disorder of the coagulation system.
Participation in another drug trial.
Pregnancy or lactation.
Persons with a state of dependence with sponsor or investigator.
Commitment to an institution.
Dementia or other psychatric disorder (e.g., drug abuse) that prevents sufficient informed consent.

Addresses

- **Primary Sponsor**

  Universitäts-Herzzentrum Freiburg - Bad Krozingen
  Mr. Prof. Dr. med. Dr. h.c. mult. Jörg Rüdiger Siewert
  Südring 15
  79189 Bad Krozingen
  Germany

  Telephone: **+49 761 270-18060**
  Fax: **+49 761 270-18070**
  E-mail: **JR.Siewert at universitaets-herzzentrum.de**
  URL: **www.herzzentrum.de**

- **Contact for Scientific Queries**

  Universitäts-Herzzentrum Freiburg Bad KrozingenKlinik für Kardiologie und Angiologie II
  Mr. PD Dr. med. Willibald Hochholzer
  Südring 15
  79189 Bad Krozingen
  Germany

  Telephone: **+49 7633 402-4285**
  Fax: **+49 7633 402-2489**
  E-mail: **willibald.hochholzer at universitaets-herzzentrum.de**
  URL: **www.herzzentrum.de**

- **Contact for Public Queries**

  Universitäts-Herzzentrum Freiburg Bad KrozingenKlinik für Kardiologie und Angiologie II

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Universitäts-Herzzentrum Freiburg Bad KrozingenKlinik für Kardiologie und Angiologie II
Mr. PD Dr. med. Willibald Hochholzer
Südring 15
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E-mail: **willibald.hochholzer at universitaets-herzzentrum.de**
URL: **www.herzzentrum.de**

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

Universitäts-Herzzentrum Freiburg - Bad KrozingenKlinik für Kardiologie und Angiologie II
Mr. Prof. Dr. Franz-Josef Neumann
Südring 15
79189 Bad Krozingen
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/03/31**

Trial Publications, Results and other documents

- Paper **Hochholzer W, Amann M, Titov A, Younas I, Löffelhardt N, Riede F, Potocnik C, Stratz C, Hauschke D, Trenk D, Neumann FJ, Valina CM. Randomized comparison of different thienopyridine loading strategies in patients undergoing elective coronary intervention – the ExcelsiorLOAD trial. JACC: Cardiovascular Interventions 2016; 9: 219-227**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*