## Trial Description

### Title

**Pharmacodynamic comparison of different oral P2Y12-receptor inhibitor loading strategies for transitioning from cangrelor in patients undergoing coronary stenting**

### Trial Acronym

**ExcelsiorLOAD2**

### URL of the trial

**[---]***

### Brief Summary in Lay Language

**Patients undergoing coronary stent implantation due to coronary stenosis require a sufficient inhibition of platelet function for prevention of coronary re-occlusions. Cangrelor is the first inhibitor of platelet function via inhibition of the ADP-receptor that can be given intravenously. Its advantage is a faster onset and offset of platelet inhibition compared to orally given durgs.**
**As patients require a continuous platelet inhibition also after the coronary intervention, the intravenous therapy with cangrelor have to be transitioned to orally given platelet inhibitors. However, the ideal point of time for the first oral loading dose is not well defined. This study aims to compare loading with Ticagrelor 180mg or Prasugrel 60mg given at start of cangrelor-infusion and before coronary intervention versus loading with Clopidogrel 600mg given directly after discontinuation of cangrelor.**

### Brief Summary in Scientific Language

**Cangrelor ist the first intravenous P2Y12-Inhibitor, which provides a significant faster onset of platelet inhibition during PCI as compared to loading with orally given P2Y12-inhibitors.**
**It has been shown that Clopidogrel can only be initiated only after discontinuation of cangrelor infusion due to an interactions between active metabolites of both agents. However, this results in a short period with reduced platelet inhibition after PCI with possible negative effects for the patient.**
**The aim of this study is to investigate different regimens with loading with Prasugrel 60mg or Ticagrelor 180mg already at the beginning of cangrelor infusion before PCI in order to achieve sufficient platelet inhibition also directly after PCI, as compared to loading with Clopidogrel 600mg after discontinuation of the cangrelor infusion.**

## Organizational Data

- DRKS-ID: **DRKS00009739**
- Date of Registration in DRKS: **2016/01/26**
- 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.: **549/15 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2015-005071-25**

## Health condition or Problem studied

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

## Interventions/Observational Groups

- Arm 1: **Kengrexal (Cangrelor), intravenous bolus of 30µg/kg followed by an infusion of 4µg/kg/min over at least 2 hours or till the end of PCI.**

  **Efient (Prasugrel), 60mg Loading dose p.o. (tablet), single dose at the beginning of PCI.**
- Arm 2: **Kengrexal (Cangrelor), intravenous bolus of 30µg/kg followed by an infusion of 4µg/kg/min over at least 2 hours or till the end of PCI.**

  **Brilique (Ticagrelor), 180mg Loading dose p.o. (tablet), single dose at the beginning of PCI.**
- Arm 3: **Kengrexal (Cangrelor), intravenous bolus of 30µg/kg followed by an infusion of 4µg/kg/min over at least 2 hours or till the end of PCI.**

  **Plavix (Clopidogrel), 600mg loading dose p.o. (tablet), single dose after discontinuation of Kengrexal-infusion.**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treament of control group)**
-

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Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

- 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 (Multiplate-Test, Roche Diagnostics) tested 1 hour after discontinuation of cangrelor.**

### Secondary Outcome

**- Proportion of patients with ADP-induced platelet aggregation beween 189 and 467 AU x min (Multiplate-Test, Roche Diagnostics)**
**- Analysis of platelet reactivity as continous variable at different time points**
**- Interaction of genetic polymorphisms (e.g. CYP2C19), clinical and laboratory variables with pharmacodynamic effects in the different treatment arms**
**- Ischemic endpoints, bleeding events**

## Countries of recruitment

- DE **Germany**

## Locations of Recruitment

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

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/26**
- Target Sample Size: **110**
-

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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

**- Hemodynamically stable patients with obstructive coronary heart disease and planned coronary stent implantation**
**- Pretreatment with aspirin**
**- Men and women over the age of 18 years**
**- Written informed consent**

### Exclusion criteria

**- Acute myocardial infarction**
**- Treatment with P2Y12-receptor inhibitor, fibrinolysis or GPIIb/IIIa inhibitor within 7 days before enrollment**
**- Contraindication for treatment with aspirin, cangrelor, clopidogrel, ticagrelor or prasugrel according to EMEA label (in particular: Allergy, Active bleeding or high bleeding risk, history of stroke or TIA, severe liver disease)**
**- Severe thrombocytopenia (<50.000/µl)**
**- Known severe disorder of the coagulation system**
**- Pregnancy or lactation**

## Addresses

- **Primary Sponsor**

**Universitäts-Herzzentrum Freiburg - Bad Krozingen**
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## Sources of Monetary or Material Support

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

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

## Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/06/07**

## Trial Publications, Results and other documents

- Trial results **Randomized Comparison of Oral P2Y12-Receptor Inhibitor Loading Strategies for Transitioning From Cangrelor: The ExcelsiorLOAD2 Trial.**

** 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.*