CABA-MiTRA-AFNET 12-DZHK34 trial

Catheter **Ab**lation for **A**F in patients with severe **Mitra**l Regurgitation after successful Transcatheter Mitral-Valve repair

ClinicalTrials.gov: NCT07380932

HYPOTHESIS

Atrial fibrillation (AF) is the most common concomitant disease in patients undergoing transcatheter edge-to-edge repair (TEER) for mitral regurgitation (MR) and detrimentally affects their outcome. While there is increasing evidence for prognostic improvement and safety of catheter ablation (CA) of AF in the overall cohort of heart failure patients, corresponding data in TEER patients are lacking.

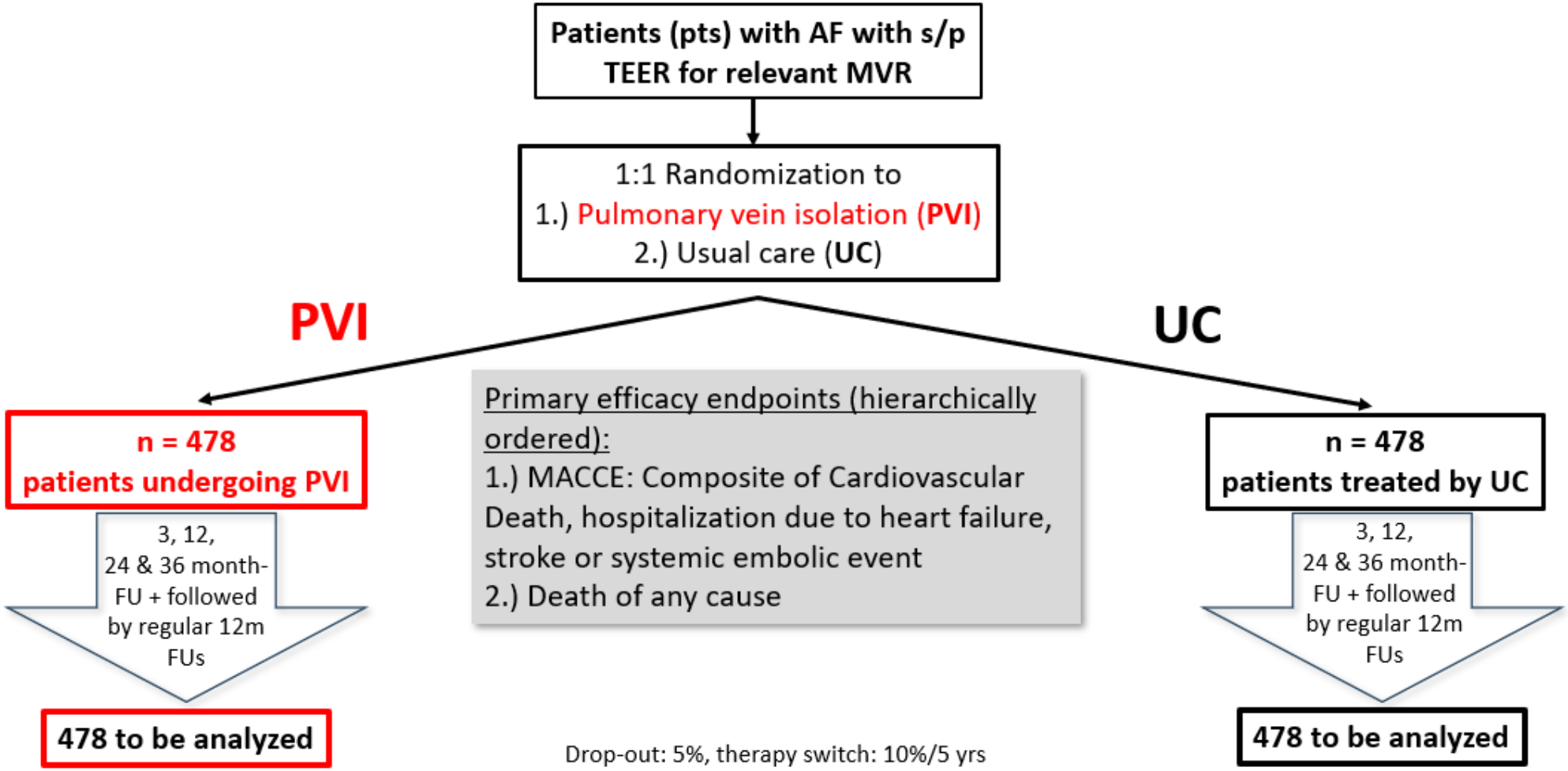
CABA-MiTRA-AFNET 12-DZHK34 will assess the hypothesis that catheter ablation of AF (after TEER) is superior to standard-of-care-treatment (after TEER) in reduction of major adverse cardiovascular and cerebrovascular events (MACCE). This multicenter prospective randomized open blinded evaluation (PROBE) trial will include patients with documented AF and successful transcatheter edge-to-edge mitral-valve repair (less than moderate MR, gradient < 5 mmHg (TEER)) for severe mitral valve regurgitation (MR).

CABA-MITRA-AFNET 12-DZHK 34 STUDY OVERVIEW

- **Study Title: C**atheter **Ab**lation for **A**F in patients with severe **Mitra**l Regurgitation after successful Transcatheter Mitral-Valve repair - **CABA-MiTRA-AFNET 12-DZHK34 trial**
- **Design:** An investigator-initiated, non-commercial, parallel-group, prospective, randomised, open, blinded endpoint assessment (PROBE), multi-centre, Therapy Strategy Trial
- **Number of patients =** 956
- **Study sites ~** 50 in Germany, with possible expansion to other countries later; approx. 0.4 patients/month/center
- **Total study duration:** 48 months of recruitment + 12 months minimum follow-up
- **Blinded Interim Analysis** after 50% of events, **Unblinded Interim Analysis** after 75% of events
- **Vanguard Phase** – ends 18 months after the start of the study (6 months preparation included)

CABA-MITRA-AFNET 12-DZHK 34 STUDY DESIGN

Multicentre prospective randomized open blinded evaluation (PROBE) design



Drop-out: 5%, therapy switch: 10%/5 yrs
power: 90% (alpha 2.5%) ; 453 events: blinded interim analysis after 50% events occurred, unblinded interim analysis after 75% events occurred

STATISTICS

Primary outcome parameters (hierarchically ordered):

1. MACCE: Composite of cardiovascular death, hospitalization due to heart failure, ischemic stroke or systemic embolic event (defined as the time to the first occurrence of any composite of the aforementioned components)
2. Death of any cause.

Key secondary outcome parameters:

Time to individual components of first primary endpoint (MACCE), QoL changes at 12 and 24 months compared to baseline (AFEQT, EQ-5D-5L, KCCQ-12), MoCA changes at 12 months compared to baseline, heart failure progression (proBNP, LV function, change of MR severity) at 12 months compared to baseline.

Assessment of safety:

Occurrence of AF ablation associated serious adverse events, hemorrhagic stroke, and non-serious adverse events of special interest - SAEs and AEoSI

AF BURDEN SUBSTUDY FOR 450 PATIENTS (ONLY FOR DEFINED ILR SUBSTUDY SITES)

- Patients who consent to an ILR implant enrolled at study sites participating in the AF burden sub-study will receive an ILR implantation in context of the clinical routine treatment or routine diagnostics, respectively.

- ILR implantation will be carried out equally in both study arms should be performed at the enrolment visit (after randomisation).

- 450 Patients will receive the ILR device “LUX-Dx™ Insertable Cardiac Monitor System” from Boston Scientific from a central study-ILR-pool managed by AFNET. The AF burden substudy will be finished when the central study ILR pool will be fully used. Logistics and provision of ILRs will be carefully linked to recruitment activities at each participating site.

- Information on AF burden is collected centrally on Boston Scientific’s Latitude platform and integrated into the study data upon completion of the study. Data from the study ILRs is not transmitted to the centers during the study.