CSI-Ulm TAVI

Clinicaltrials.gov NCT02162069

1. Title

Coronary and structural interventions Ulm – transcatheter aortic valve implantation

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This is a prospectiv and single center study.

2. Protocol summary

Aim of this study is the evaluation of acute and long-term outcomes after transcatheter aortic valve implantation at the University of Ulm, Ulm, Germany.

All outcome data will be evaluated according to the VARC-2 criteria (J Am Coll Cardiol 2012;60:1438–54):

Table 2 Mortality

All-cause mortality
Cardiovascular mortality
Any of the following criteria:
Death due to proximate cardiac cause (e.g. myocardial infarction, cardiac tamponade, worsening heart failure)
Death caused by non-coronary vascular conditions such as neurological events, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular disease
All procedure-related deaths, including those related to a complication of the procedure or treatment for a complication of the procedure
All valve-related deaths including structural or non-structural valve dysfunction or other valve-related adverse events
Sudden or unwitnessed death
Death of unknown cause
Non-cardiovascular mortality
Any death in which the primary cause of death is clearly related to another condition (e.g. trauma, cancer, suicide)

Table 3 Myocardial Infarction

Peri-procedural MI (<72 h after the index procedure)

- New ischemic symptoms (e.g. chest pain or shortness of breath), or new ischemic signs (e.g. ventricular arrhythmias, new or worsening heart failure, new ST-segment changes, hemodynamic instability, new pathological Q-waves in at least two contiguous leads, imaging evidence of new loss of viable myocardium or new wall motion abnormality) AND
- Elevated cardiac biomarkers (preferable CK-MB) within 72 h after the index procedure, consisting of at least one sample post-procedure with a peak value exceeding 15 x as the upper reference limit for troponin or 5 x for CK-MB.* If cardiac biomarkers are increased at baseline (>99th percentile), a further increase in at least 50% post-procedure is required AND the peak value must exceed the previously stated limit

Spontaneous MI (>72 h after the index procedure)

- Any one of the following criteria
- Detection of rise and/or fall of cardiac biomarkers (preferably troponin) with at least one value above the 99th percentile URL, together with the evidence of myocardial ischemia with at least one of the following:
  - Symptoms of ischemia
  - ECG changes indicative of new ischemia [new ST-T changes or new left bundle branch block (LBBB)]
  - New pathological Q-waves in at least two contiguous leads
  - Imaging evidence of a new loss of viable myocardium or new wall motion abnormality
- Sudden, unexpected cardiac death, involving cardiac arrest, often with symptoms suggestive of myocardial ischemia, and accompanied by presumably new ST elevation, or new LBBB, and/ or evidence of fresh thrombus by coronary angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood.
- Pathological findings of an acute myocardial infarction

Table 4 Stroke and TIA

Diagnostic criteria

- Acute episode of a focal or global neurological deficit with at least one of the following: change in the level of consciousness, hemiplegia, hemiparesis, numbness, or sensory loss affecting one side of the body, dysphasia or aphasia, hemianopia, amaurosis fugax, or other neurological signs or symptoms consistent with stroke
- Stroke: duration of a focal or global neurological deficit >24 h; OR <24 h if available neuroimaging documents a new haemorrhage or infarct; OR the neurological deficit results in death
- TIA: duration of a focal or global neurological deficit <24 h, any variable neuroimaging does not demonstrate a new hemorrhage or infarct
- No other readily identifiable non-stroke cause for the clinical presentation (e.g. brain tumour, trauma, infection, hypoglycemia, peripheral lesion, pharmacological influences), to be determined by or in conjunction with the designated neurologist*
- Confirmation of the diagnosis by at least one of the following:
  - Neurologist or neurosurgical specialist
  - Neuroimaging procedure (CT scan or brain MRI), but stroke may be diagnosed on clinical grounds alone

Stroke classification

- Ischemic: an acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of the central nervous system tissue
- Hemorrhagic: an acute episode of focal or global cerebral or spinal dysfunction caused by intraparenchymal, intraventricular, or subarachnoid hemorrhage
- A stroke may be classified as undetermined if there is insufficient information to allow categorization as ischemic or haemorrhagic

Stroke definitions†

- Disabling stroke: an mRS score of 2 or more at 90 days and an increase in at least one mRS category from an individual's pre-stroke baseline
- Non-disabling stroke: an mRS score of <2 at 90 days or one that does not result in an increase in at least one mRS category from an individual's pre-stroke baseline

Table 11 Composite Endpoints

Device success
Absence of procedural mortality AND
Correct positioning of a single prosthetic heart valve into the proper anatomical location AND
Intended performance of the prosthetic heart valve (no prosthesis- patient mismatch* and mean aortic valve gradient <20 mmHg or peak velocity <3 m/s, AND no moderate or severe prosthetic valve regurgitation*)
Early safety (at 30 days)
All-cause mortality
All stroke (disabling and non-disabling)
Life-threatening bleeding
Acute kidney injury—Stage 2 or 3 (including renal replacement therapy)
Coronary artery obstruction requiring intervention
Major vascular complication
Valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR)
Clinical efficacy (after 30 days)
All-cause mortality
All stroke (disabling and non-disabling)
Requiring hospitalizations for valve-related symptoms or worsening congestive heart failure‡
NYHA class III or IV
Valve-related dysfunction (mean aortic valve gradient >20 mmHg, EOA <0.9-1.1 cm^{2}† and/or DVI <0. 35 m/s, AND/OR moderate or severe prosthetic valve regurgitation*)
Time-related valve safety
Structural valve deterioration
Valve-related dysfunction (mean aortic valve gradient >20 mm Hg, EOA <0.9–1.1 cm^{2}‡ and/or DVI <0.35 m/s, AND/ OR moderate or severe prosthetic valve regurgitation*)
Requiring repeat procedure (TAVI or SAVR)
Prosthetic valve endocarditis
Prosthetic valve thrombosis
Thrombo-embolic events (e.g. stroke)
VARC bleeding, unless clearly unrelated to valve therapy (e.g. trauma)

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