PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

WATCH Bleeding Episodes After Left Atrial Appendage Occlusion Versus Usual Care in Patients With Atrial FIBrillatIon and Severe to eNd-stage Chronic Kidney Disease (WatchAFIB in CKD)

Trial Acronym

WatchAFIB

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to evaluate the superiority of left atrial appendage occlusion in comparison to oral anticoagulation with a vitamin K antagonist (INR 2-3) related to the frequency of occurrence of at least one bleeding classified as moderate or major within 24 months.

Brief Summary in Scientific Language

Open, randomized, controlled, multicenter clinical investigation. Transesophageal echocardiography (TEE) for all patients within 14 days of the Enrolment Visit. Patients randomized to oral anticoagulation (OAC) will receive standard of care (SOC) vitamin K antagonist treatment throughout the 24 months clinical investigation period, managed by the primary care physician, with the goal of achieving and maintaining an INR of 2-3 (INR monitoring by the primary care physician every two weeks throughout study period).

Patients randomized to the WATCHMAN device will undergo device implantation within 48 hours of the screening TEE and after confirmation of INR ≤ 1.7 in the catheterization laboratory with a subsequent hospitalization for 24-48 hours.

Concomitant treatment with Aspirin/Clopidogrel (managed by the patient's

primary care
physician) will be initiated on the day prior to device implantation, and will be continued
for 6 months after the procedure, at which time Clopidogrel will be discontinued;
administration of Aspirin will be continued indefinitely.

Follow-up visits for all patients will take place on Day 45, and at Month 6, Month 12 and
Month 24 (End of Study). Routine safety and efficacy assessments at each visit will be the
same for all patients regardless of treatment group.

Follow-up- visits at day 45, months 6, 12 and 24. Patients randomized to the WATCHMAN device
will have additional TEE imaging performed at the Day 45 and Month 6 visits.

An independent Data Monitoring Committee will monitor safety. A blinded and independent
Endpoint Committee will evaluate end-points throughout the entire study period.

Organizational Data

- DRKS-ID: **DRKS00005889**
- Date of Registration in DRKS: **2015/02/20**
- Date of Registration in Partner Registry or other Primary Registry: **2014/01/15**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02039167 (ClinicalTrials.gov)**
- Sponsor-ID: **OVGU-014-Kar (University of Magdeburg)**

Health condition or Problem studied

- Free text: **Blood Coagulation Disorders**
- Free text: **Atrial Fibrillation**
- Free text: **Thrombosis of Left Atrial Appendage**
- Free text: **Chronic Kidney Disease Stage 4**
- Free text: **Chronic Kidney Disease Stage 5**

Interventions/Observational Groups

- Arm 1: **Device: Left atrial appendage occlusion**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Frequency of occurrence of moderate and major bleedings (Type 2 to Type 5 according to the Bleeding Academic Research Consortium (BARC) definitions); time frame: 24 months

Secondary Outcome

- Frequency of at least one occurrence of a combined endpoint of moderate or major bleeding and/or severe cardiovascular adverse events (stroke, cardiac infarction, thrombosis, death); time frame: 24 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Otto-von-Guericke University Magdeburg, Faculty of Medicine, Magdeburg**
- **Zentralklinik Bad Berka - Klinik für Kardiologie, Bad Berka**
- **CCB im Markus Krankenhaus Frankfurt, Frankfurt**

- **Medizinische Hochschule Hannover Zentrum Innere Medizin, Abt. Kardiologie und Angiologie, Hannover**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/01/31**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

- Paroxysmal, persistent, or permanent non-valvular atrial fibrillation (AF), documented by electrocardiography performed at screening or within the prior 6 months

- Indication for oral anticoagulation as assessed by CHA2DS2-VASc-Score (≥ 2)

- Severe to end-stage chronic kidney disease (eGFR < 30 ml/min as determined by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula)

- 18 to 80 years, inclusive

- Life expectancy of at least 2 years

- Negative pregnancy test for women

- Capable of understanding the investigational nature, potential risks and benefits of the study, and able to provide valid informed consent

- Written informed consent

Exclusion criteria

- AF due to a reversible cause or a singular occurrence of AF

- Conditions other than AF that require anticoagulation

- Transient ischemic attack or stroke within previous 3 months

- A need for Aspirin (at a dose of > 162.5 mg/day) or for both Aspirin and Clopidogrel/other antiplatelet drugs (daily administration) other than for clinical investigation

- Contraindications or allergies to vitamin K antagonists, Aspirin or Clopidogrel

- Previous closure (surgical, interventional) of the left atrial appendage (LAA)

- Previous closure of atrial septal defect (ASD) / persistent foramen ovale (PFO)

- Active internal bleeding

- Thrombocytopenia (< 100,000 platelets/mm3)

- History of or planned organ transplantation

- Planned Mitra Clip or transcatheter aortic valve implantation (TAVI) intervention

- Planned cardiac surgery

- History of intracranial, intraocular or retroperitoneal bleeding

- Severe GI-bleeding within the last 3 months

- Hemorrhagic gastro-intestinal diseases (e.g., ulcerative colitis)

- History of or condition associated with increased bleeding risk

- Uncontrolled arterial hypertension

- Heparin-induced thrombocytopenia type II

- Known inherited coagulation disorders

- Severe liver dysfunction (spontaneous INR > 1.5) or liver cirrhosis ≥ CHILD B

- Chronic use of non-steroidal anti-inflammatory drugs (NSAIDs)

- Women who are planning to become pregnant, or who are breastfeeding

- Active infection of any kind

Transesophageal echocardiography (TEE) Exclusion Criteria

- Intracardiac thrombus or dense spontaneous echo contrast as visualized by TEE (with use of sonovue in suspicious cases)

- **Significant mitral valve stenosis**
- **Any congenital heart disease, including atrial septal defect**
- **Pericardial effusion during ECHO assessment of > 2 mm**
- **Cardiac tumor**

Addresses

■ **Primary Sponsor**

University of Magdeburg

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***

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

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2014/12/02

** 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.*