Trial Description

Title

Catheter ablation of typical right atrial flutter (BK-Gold study) - Comparison between two irrigated ablation catheters (Platin/Iridium- versus Gold-tip)

Trial Acronym

BK-Gold

URL of the trial

http://---

Brief Summary in Lay Language

Typical atrial flutter can nowadays be treated with a highly successfull catheter ablation procedure.
Various ablation catheters are available for this procedure. In this study, two approved standard catheters will be compared in their effectiveness. For this study project catheters with a gold tip or, alternatively, catheters with a platinum / iridium tip will be compared. Catheters with gold tips have the theoretical advantage of the improved heat conduction properties and the improved energy delivery to the tissue. This should allow a more effective ablation, which should also result in a shorter procedure time. Previous studies did not show a significant difference in these catheter-types, if so-called "uncooled" catheters were used. In our study, however, "cooled" ablation catheters will be used. Cooled ablation catheters have two major advantages. On the one hand, they reduce the overheating of the catheter tip by cooling, which results in reduced clot formation. On the other hand, energy delivery to the tissue can be further improved, which can make the ablation lesion more effective. Our hypothesis is that cooled gold catheters can provide more effective ablation by both the cooling and the improved heat conduction properties of the gold. We therefore expect a shorter treatment time and a higher acute success rate. We also want to be able to make statements about the long-term success rate by tracking our patients.

Brief Summary in Scientific Language

The interventional treatment of typical right atrial flutter is a standard procedure with a high success rate (> 90%) and a low recurrence rate (<10%) (1). Despite these favorable treatment data, a further improvement is possible. This seems possible in particular by the use of gold catheters, which have better heat conduction properties and thus can produce a better ablation energy transfer to the tissue. This should allow a more effective ablation, which should also result in a shorter procedure time. Comparisons between uncooled gold and the standard platinum / irridium catheters have shown no difference in the ablation duration during right atrial flutter ablation procedures (1, 2). For several years, cooled gold catheters have also been available for ablation treatment (3). In this research project, we will now prospectively compare the use of cooled gold catheters with cooled platinum / irridium catheters in cavo-tricuspidal isthmus ablation procedures for the treatment of typical atrial flutter. Cooled catheters have two major advantages. On the one hand, cooling reduce the overheating of the

catheter tip, which results in a reduced clot formation and thus a reduced thromboembolization rate. On the other hand, energy delivery to the tissue can be improved, which can make the ablation procedure more effective. Our hypothesis is that cooled gold catheters can provide more effective ablation by both the cooling and the improved heat conduction properties of the gold. Correspondingly, we expect a shorter ablation time, a higher energy transfer to the tissue and a higher acute success rate. We also want to make statements about the long-term recurrence rate via the clinical follow-up. A disadvantage of cooled catheters is that the measured temperature at the catheter tip does not correspond to the tissue temperature, thus increasing the risk of tissue overheating / "steam pops". Because of the improved heat conduction properties of gold, this catheter has to be flushed less, therefor we expect a lower "steam-pop" rate (4) for this catheter type.

References

1.Gold vs. platinum–iridium tip catheter for cavotricuspid isthmus ablation: the AURUM 8 study. Lewalter T et. al., Europace (2011) 13, 102–108.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013003**
- Date of Registration in DRKS: **2017/09/08**
- 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.: **298/17 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I48.3 - Typical atrial flutter**

Interventions/Observational Groups

- Arm 1: **Ablation of atrial flutter with cooled gold catheter**
- Arm 2: **Ablation of atrial flutter with cooled platin/irridium catheter**

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: **Treatment**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Ablation time until success of the ablation procedure (bidirectional isthmus block)

Secondary Outcome

a. Ablation time until termination of atrial flutter
b. Total energy delivery up to the termination as well as to the final success of the ablation procedure (bidirectional isthmus block)
c. Mean / minimum / maximum catheter temperature during ablation therapy
d. Volume of applied rinsing solution (ablation catheter cooling)
e. Acute recovery rate in the 30-minute waiting period
f. Tissue overheating / "steam-pop" rate
g. Complications
h. Recurrence of typical right atrial flutter in follow-up (6 months)

a. Ablation time until termination of atrial flutter
b. Total energy delivery up to the termination as well as to the final success of the ablation procedure (bidirectional isthmus block)
c. Mean / minimum / maximum catheter temperature during ablation therapy
d. Volume of applied rinsing solution (ablation catheter cooling)
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f. Tissue overheating / "steam-pop" rate
g. Complications
h. Recurrence of typical right atrial flutter in follow-up (6 months)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Universitäts-Herzentrum Freiburg-Bad Krozingen (Standort: Bad Krozingen), Bad Krozingen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2017/09/11**
- Target Sample Size: **80**
- 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

• Patients who have documented typical right atrial flutter and who are scheduled for a catheter ablation procedure

• Men and women at least 18 years of age

Exclusion criteria

- age below 18 years

- contraindication to a catheter ablation procedure

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

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

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Status

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

Trial Publications, Results and other documents

** 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.*