The Tailored-AF trial

Tailored vs. anatomical ablation strategy for Persistent **AF**

ClinicalTrials.gov: NCT04702451

Internet site: www.volta-medical.com

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Enrollment Status

1st patient enrolled on Feb. 12, 2021
To date, 301/374 patients enrolled
in 25 EU/US sites

80% enrollment completed!

Top 3 sites with highest number of patients enrolled:

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Study Web Tools

eCRF

ECG Atrium Webportal

Tailored-AF app

For France only:

Reimbursement System

Transport Reservation

CIP ID: CLIPL-01-002
CIP Revision: D

Version 3.4
5-Jul-22

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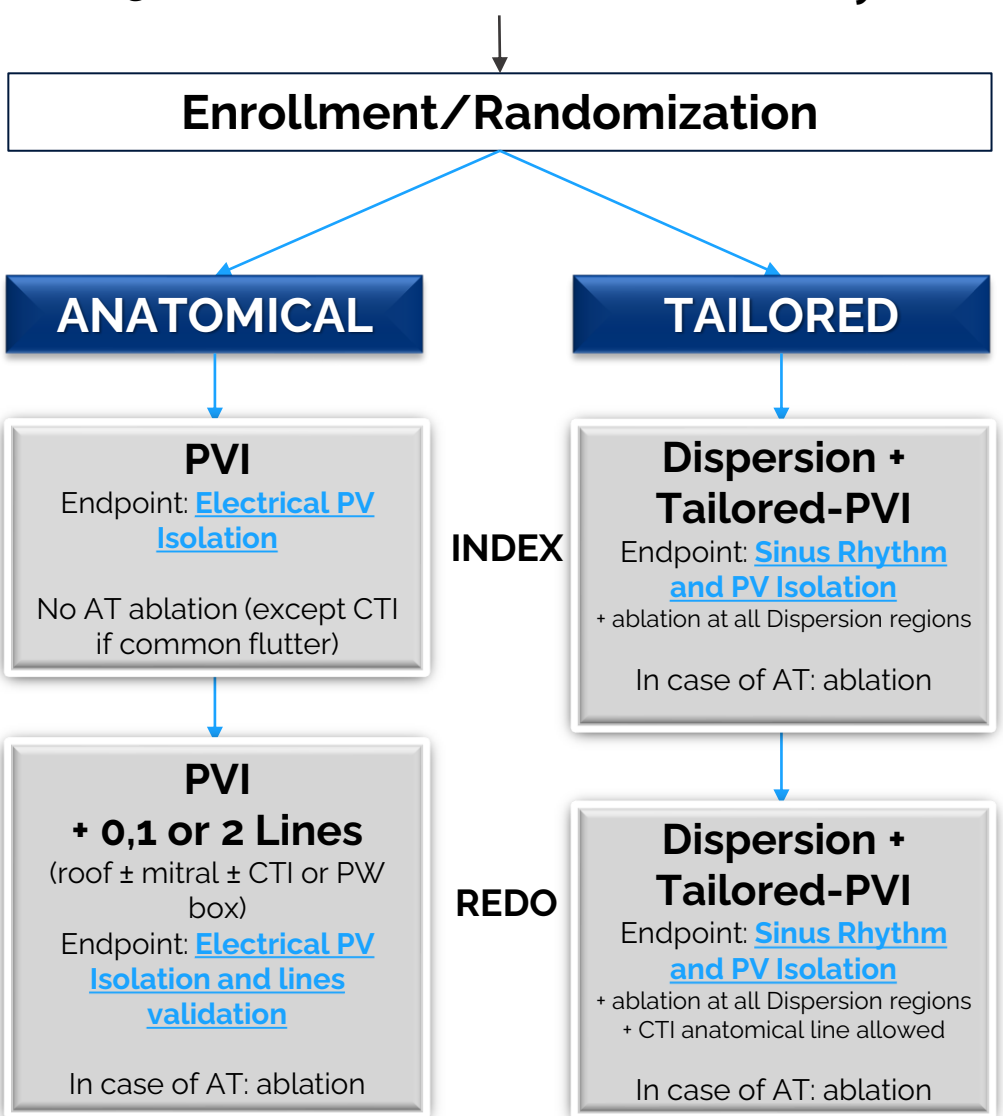
Ablation Protocol

EU: 3 months ≤ *de novo* **Persistent AF** ≤ ***5 years***
US: 3 months ≤ *de novo* **Persistent AF** < ***1 year***



Only 1 redo within corresponding ablation protocol for multiple procedures endpoints

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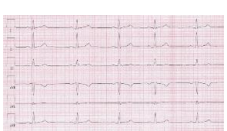
Study Flowchart

ENROLLMENT

Baseline Visit:
Informed consent
Patient demographics, physical examination
AF maximal sustained duration / cardioversions (ECGs, physician's letter)
Patient cardiac medication assessment
12-lead ECG, QoL assessment, Kardia supply

ABLATION

FOLLOW-UP



3-mo FU visit
AF/AT recurrence assessment
Patient cardiac medication assessment
12-lead ECG + 24h holter
QoL assessment, adverse events

6-mo FU visit
AF/AT recurrence assessment
Patient cardiac medication assessment
12-lead ECG + 24h holter
QoL assessment, adverse events

12-mo FU visit
AF/AT recurrence assessment
Patient cardiac medication assessment
12-lead ECG + 24h holter
QoL assessment, adverse events

1 Kardia ECG weekly / if symptoms

In the event of a recurrence, schedule your patients for a repeat ablation before the end of the 9th month

Independent blinded ECG analysis by

BANOOK GROUP

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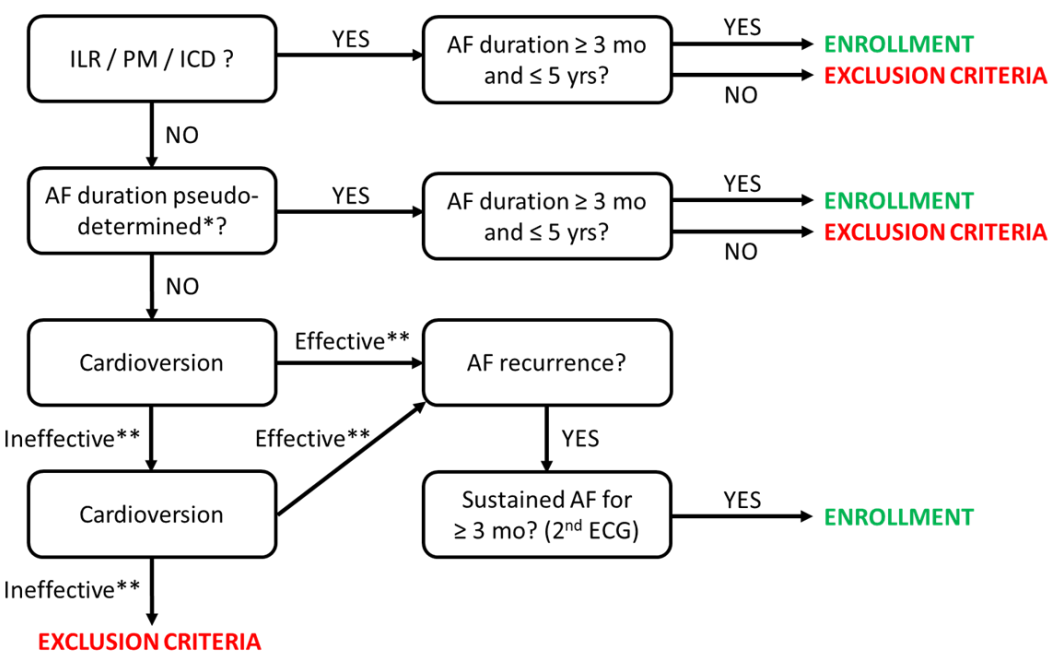
Main Inclusion Criteria

- Patients 18 years of age or older, candidates for a first AF ablation
- Persistent AF (EU/US) or long-standing persistent AF (EU only)

A documentation of sustained AF for at least 3 months is mandatory (documentation with ECG, holters, physician's letter)



*AF duration pseudo-determined means that there are clear indications of AF duration, i.e., the patient has been followed-up with regular ECGs
**An effective cardioversion means that sinus rhythm has been restored at the end of the procedure and last ECG before discharge in sinus rhythm

An ineffective cardioversion means that sinus rhythm could not be restored at the end of the procedure or last ECG before discharge in AF

If AF duration is pseudo-determined, cardioversion is allowed, but no waiting should be performed post-cardioversion

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Exclusion Criteria 1/2

1. **Paroxysmal and short-standing AF < 3 months**
2. **Long-standing persistent AF > 5 years (EU) or ≥ 1 year (US)**
3. ≥ 2 previous ineffective cardioversion **sessions** **in case of undetermined AF duration**
4. **Severe obesity (BMI > 40)**
5. **Very dilated Left Atrium (e.g., LA diameter > 60 mm and/or LA surface > 40 cm² determined by 2D echo)**
6. Patients with AF **secondary** to an obvious reversible cause
7. **Inadequate anticoagulation** as defined in the inclusion criteria
8. **LA thrombus** on TEE (EU/US) or CT Scan (only for EU) prior to procedure
9. Contraindications to anticoagulation
10. Patients who are or may potentially be **pregnant**
11. **Previous surgical or catheter ablation for AF**
12. Any **cardiac surgery** within the past 2 months (60 days)
13. **Myocardial infarction** within the past 2 months (60 days)
14. Previous **AV valve (mitral or tricuspid)** surgery
15. History of blood clotting or bleeding abnormalities
16. Documented **arterial** thromboembolic event (including TIA) within the past 12 months (365 days)

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Exclusion Criteria 2/2

17. **Rheumatic** Heart Disease
18. Chronic severe Heart Failure (**NYHA IV and/or LVEF < 25%**)
19. Awaiting **cardiac transplantation** or other cardiac surgery within the next 12 months (365 days)
20. Unstable **angina** within the past month
21. Acute illness or active **systemic infection** or sepsis
22. AF **secondary** to electrolyte imbalance, thyroid disease, or reversible or non-cardiac cause
23. Diagnosed atrial **myxoma**
24. Significant severe **pulmonary disease** (GOLD stage IV of COPD) or any other disease or malfunction of the lungs or respiratory system that produces chronic symptoms (e.g., **unstable or untreated sleep apnea**)
25. Significant congenital anomaly or medical problem that in the **opinion of the investigator** would preclude enrollment
26. Enrollment in an **investigational** study evaluating another device, biologic, or drug
27. Presence of intramural **thrombus, tumor or other abnormality** or condition that precludes vascular access, or manipulation of the catheter
28. Life expectancy or other disease processes likely to limit **survival to less than 12 months**
29. Acute **Covid-19** infection (fever and/or biological inflammatory syndrome, and positive test documented)

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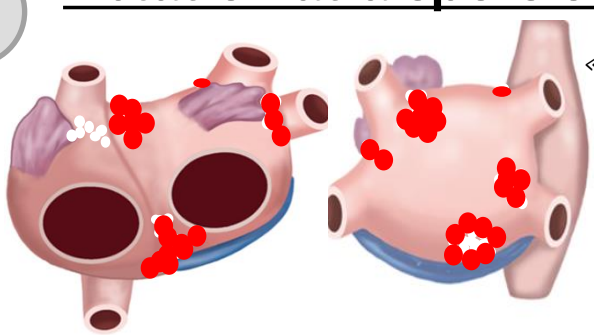
The Tailored Protocol

1 Bi-atrial AF mapping

Guided by VX1, thorough and high density

Remapping and reablation if needed

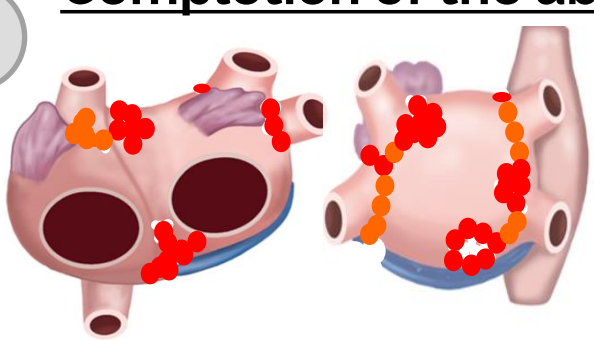
2 Ablation at dispersion areas



« Ablate & connect » and/or
« Circle & connect »
+ « Tailored PVI »
+ subsequent AT ablation

Primary Endpoint: Sinus rhythm conversion

3 Completion of the ablation set



Endpoints:
- Ablation & connection of all dispersion areas
- Electrical PV isolation
- Electrical isolation of encircled areas
- Line validation for documented macroreentry

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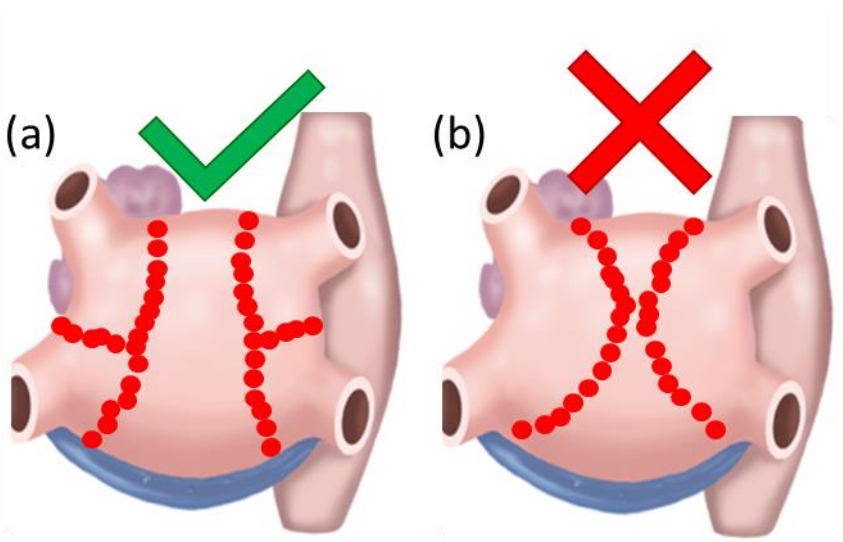
Anatomical arm ablation

Procedural endpoint = **isolation of all four PVs** documented by mapping catheter and by creating a contiguous circular lesion around each pulmonary vein antrum with point-by-point applications of RF energy.

DC shock will be performed at the end of the procedure if needed.

RF applications at the carinas are allowed (a)

No RF applications outside the PV antra are allowed (b)



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Medication guidelines

Pre-ablation:

- AADs should be stopped before ablation
- **Continuous anticoagulation for >4 weeks prior to ablation is mandatory**

Intraprocedural:

- Anticoagulation consistent with your standard practice should be used
- Heparin should be administered prior to or immediately following transseptal puncture, and adjusted to achieve and maintain an ACT of at least 300 seconds

Post-ablation:

- Systemic anticoagulation is recommended for at least 2 months after the procedure
- AADs are allowed for the first 3 months (post-ablation blanking period) **but discontinuation is required at 3 months**
- **The use of diuretics prophylactically, especially for long procedures regardless of the study arm, is recommended**

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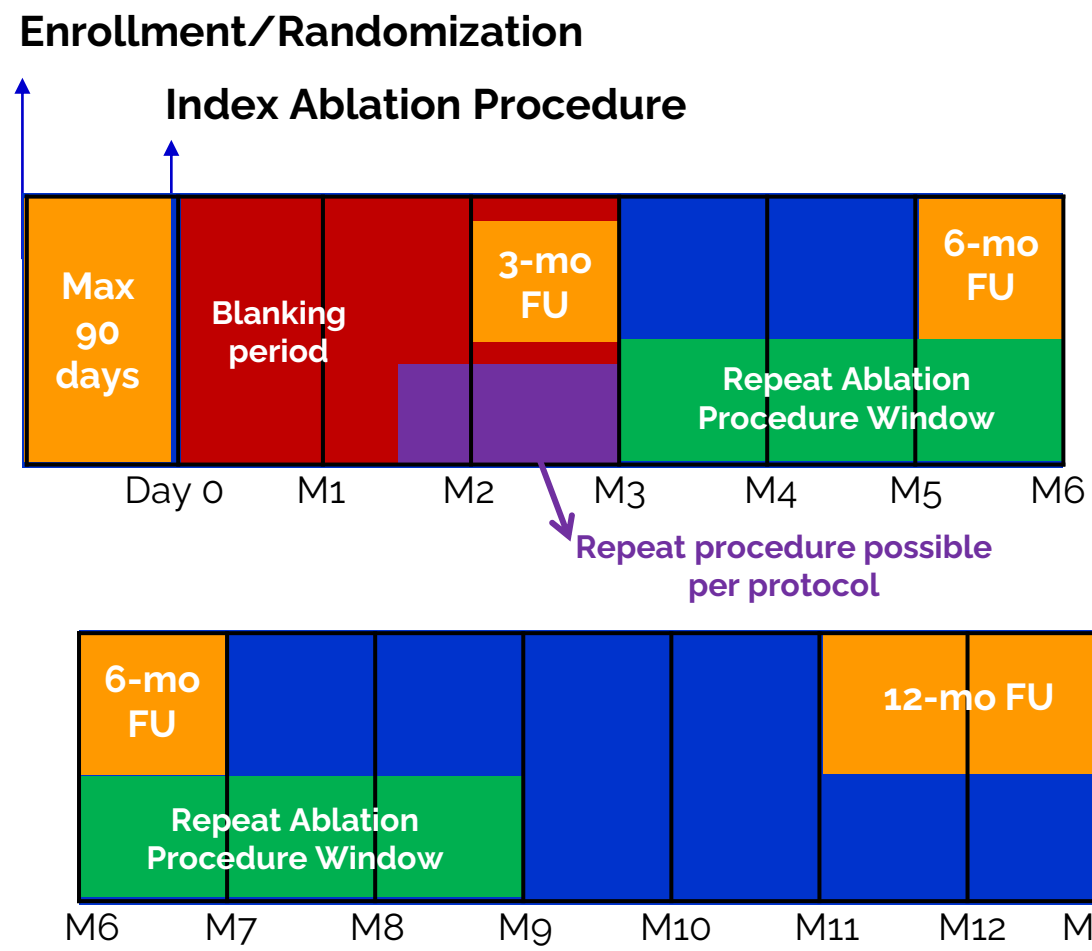
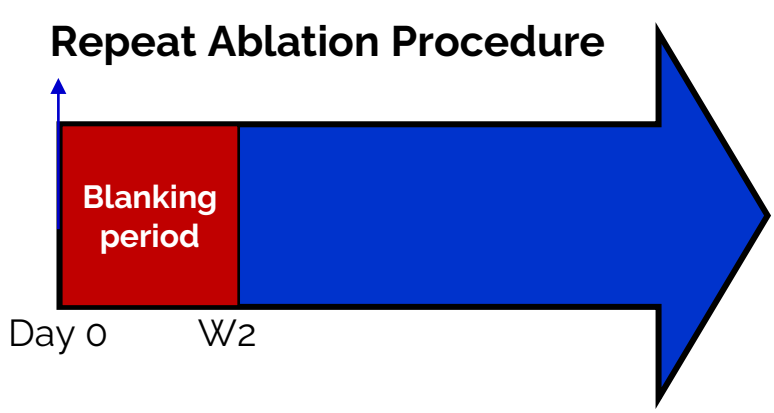
Windows and blanking periods





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