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Inflammation, oxidative stress and wound healing after ablation of atrial fibrillation

Submission date	Recruitment status	[ ] Prospectively registered
27/11/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/05/2019	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07098 (ref. no. of The Medical-Scientific Fund of the Mayor of Vienna)

Study information

Scientific Title
Time course of biochemical markers of inflammation, oxidative stress and wound healing after ablation of atrial fibrillation

Study objectives
1. Radiofrequency ablation of Atrial Fibrillation (AF) affects biochemical markers of inflammation, oxidative stress and wound healing
2. The ablation-induced changes of the assessed biochemical markers correlate with the ablation-induced structural changes, with the amount of energy applied during ablation and with the AF recurrence rate after ablation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the Medical University of Vienna on the 13th February 2007 (ref: 028/2007) - www.meduniwien.ac.at/ethik.

Study design
Observational, prospective, single centre, longitudinal study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Atrial fibrillation

Interventions
Observational trial:
The included patients will undergo a radiofrequency ablation procedure comprising:
1. A CARTO-guided left atrial circumferential ablation
2. A Lasso-guided segmental pulmonary vein isolation, and
3. Ablation of complex fractionated potentials

Venous blood sampling will be performed before and 6 hours, 24 hours, 48 hours, 7, 28, 90 and 180 days after ablation in order to determine biochemical markers of inflammation, wound healing and oxidative stress. Transthoracal echocardiography and cardiac MRI will be conducted before and 6 months after ablation in order to assess ablation-induced structural changes. Successful ablation will be defined as no recurrence of atrial fibrillation persisting or developing beyond a period of 3 months after ablation.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Biochemical markers of inflammation, oxidative stress and wound healing at the above specified timepoints
2. Ablation-induced structural atrial changes evaluated by MRI and echocardiography at the above specified timepoints

Secondary outcome measures
1. Correlation of the assessed biochemical markers with ablation-induced structural changes, energy application data and AF recurrence rate after ablation
2. Complications

Overall study start date
30/11/2007

Completion date
01/08/2008

Eligibility

Key inclusion criteria
1. Genders eligible for study: both
2. Age older than 18 years
3. Symptomatic, drug-resistant paroxysmal atrial fibrillation (self-terminating episodes lasting less than 7 days)
4. Patients referred to our department for catheter ablation of atrial fibrillation
5. Adequate anticoagulation for at least 1 month prior to admission (oral anticoagulation (target International Normalised Ratio [INR] 2 to 3) or treatment with weight-adjusted low-molecular-weight heparin

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Pregnancy
2. Ongoing infections
3. Intracardiac thrombosis detected by trans-oesophageal echocardiography
4. Contraindications to anticoagulation
5. History of myocardial infarction or cardiac surgery within the last 3 months prior to admission
6. Pacemaker or other contraindications to Magnetic Resonance Imaging (MRI)
7. Denial or withdrawal of informed consent
8. Life expectancy less than 1 year

Date of first enrolment
30/11/2007

Date of final enrolment
01/08/2008

Locations

Countries of recruitment
Austria

Study participating centre
Waehringer Guertel 18-20
Vienna
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Sponsor information

Organisation
Medical University of Vienna (Austria)

Sponsor details
Department of Internal Medicine II
Division of Cardiology
Währinger Gürtel 18-20
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Sponsor type
University/education

Website
http://www.meduniwien.ac.at/

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Government

Funder Name
The Medical-Scientific Fund of the Mayor of Vienna (Medizinisch-Wissenschaftlicher Fonds des Burgermeisters der Bundeshauptstadt Wien) (Austria) (ref: 07098) - http://www.wien.gv.at/fonds/gesundheit/index.htm

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/10/2011	31/05/2019	Yes	No
Results article	results	01/03/2012	31/05/2019	Yes	No