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Comparison of COOL-Tip catheters vs Usual 4 mm catheters for radiofrequency ablation of accessory pathways and idiopathic ventricular arrhythmias

Submission date
23/01/2013

Recruitment status
No longer recruiting

Registration date
16/05/2013

Overall study status
Completed

Last Edited
01/09/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to compare the efficiency between catheters used for radiofrequency ablation (RFCA), a procedure to correct irregularity in the heart rhythm, of accessory pathways in the heart and irregular heartbeat (arrhythmia). Our goal is to find the best catheter and energy settings for different locations of irregularity (arrhythmic focus). For many years, non-irrigated tip catheters have been used for this procedure. Irrigated-tip catheters work better and have fewer risks of blood clot. We want to look at whether COOL-Tip catheters can be used as a universal catheter for all locations and whether they work faster.

Who can participate?
The study aims to recruit about 200 patients, both male and female of age > 18 years from 4 Polish hospitals: Warsaw, Wroclaw, Radom and Ostrowiec Swietokrzyski.

What does the study involve?
Patients will be randomly allocated to two groups: one receiving treatment with COOL-Tip catheters and the other with the usual 4mm catheters. Patients will be followed for 12 months after the procedure. Arrhythmia or ACP recurrence data, information about the course of the procedure and information regarding early and late complications will be collected. Observation will include follow-up visits 1, 6 and 12 months after the RFCA procedure. A standard internet-based database will be provided to all participating sites. It will include standard electronic study forms and documentation of the clinical status of the patient. Follow-up visits will be conducted by an electrophysiology specialist in an outpatient setting. Before each follow-up visit, a 24-hour Holter test (to continuously record the heart's rhythms) will be scheduled. In case of undocumented pounding or racing of heart, typical of the ablated arrhythmia, the patient shall receive an arrhythmia recorder to confirm the recurrence of the ablated arrhythmia. If information could not be collected during follow-up visits, it will be recorded by a qualified nurse during analysis of the patient files, the patients family files, medical data and medical files kept by the general practitioner/treating physician.

What are the possible benefits and risks of participating?
Performance of the procedure by an experienced specialist will be the benefit for the patient, regardless of the random group assignment. Upon inclusion in the study, the patient benefits from contact and follow-up visits within 12 months of the procedure, conducted directly by the specialist performing the ablation procedure. Approved catheters bearing the CE mark will be used during the study. The risk is limited to standard complications connected with ablation procedures.

Where is the study run from?
The study is run from the Regional Specialist Hospital, Research and Development Centre, Wroclaw (Poland).

When is the study starting and how long is it expected
The recruitment starts in March 2013. Patients will be enrolled in the study for a period of one year.

Who is the main contact?
Dr Sebastian Stec
smstec@wp.pl

Contact information

Type(s)
Scientific

Contact name
Dr Sebastian Stec

Contact details
Obroncow Tobruku 19/92
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01-474

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ELM-1

Study information

Scientific Title
A prospective, randomized comparison of COOL-Tip catheters vs Usual 4 mm catheters for radiofrequency ablation of accessory pathways and idiopathic ventricular arrhythmias

Study objectives
A COOL-Tip catheter may show better efficacy and shorter time of achievement of the procedure endpoint when used for all types and locations of ACP, ACP-T and idiopathic premature ventricular contractions (PVC) / ventricular arrhythmias (VT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Board Name: Komisja Bioetyczna OIL Rzeszow, ul. Reformacka 10, 35-026 Rzeszow, Poland, 27/04 /2012, ref: 05/2012/B

Study design
Randomized prospective multicentre single-blinded active control study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Accessory pathways and idiopathic ventricular arrhythmias

Interventions
1:1 randomization to COOL-Tip catheters and usual 4 mm catheters for ablation.

Efficacy of RFCA within 300 or 600 sec of radiofrequency energy delivery for treatment of ACP, ACP-T and idioapathic PVC/CT

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Procedural success rate; 300 sec of radiofrequency energy application; procedural success rate wtihin 300 sec of radiofrequency energy application (total ablation time <300 sec)
2. Need for cross-over; 300 sec radiofrequency energy applications with suboptimal power or impedance or after 600 sec of failed radiofrequency energy application with optimal parameters of mapping and RF energy supply; need for additional use of COOL-Tip catheter (in usual 4 mm tip group) or additional COOL-Tip catheter in COOL-Tip group

Secondary outcome measures

1. Procedural success rate; 600 sec of radiofrequency energy application; procedural success rate within 600 sec of radiofrequency energy application (total ablation time<600 sec).
2. Cumulative duration of ablation energy delivery (sec); periprocedural
3. RF ablation time (sec); periprocedural
4. Duration of fluoroscopic exposure (min); periprocedural
5. Procedural duration (min); periprocedural
6. Early procedural complication rate within 24 hours after procedure
7. Late camplication rate 24 hours to 12 months after procedure

Overall study start date
31/01/2013

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Accessory pathway or idiopathic PVC/VT qualified for ablation
2. Electrophysiologically confirmed arrhythmia mechanism and procedure endpoint
3. Age above 18 years, either sex
4. Signed patient informed consent for participation in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200 patients. 2 arms: COOL-Tip catheter n=100 patients vs usual catheters 4mm n=100 patients

Key exclusion criteria
1. Planned AF or AFL ablation
2. Second procedure for arrhythmia
3. Acute coronary syndrome or myocardial infarction within the preceding 3 months
4. Acute reversible arrhythmia causes (such as myocarditis)
5. Advanced, haemodynamically significant valvular heart disorders
6. Status post heart valvular surgery and atrial septal defect (ASD) closure
7. Planned cardiac surgery within the upcoming 6 months
8.Inconsistent medication use within 7 days before enrolment into the study
9. Advanced heart failure [class IV according to New York Heart Association (NYHA)]
10. Lactating or pregnant women
11. Recreational drugs or alcohol addiction

12. Inability to take part in long-term observation and follow-up visits
13. Limited sanity and limited legal capacity
14. Participation in another clinical study
15. Right-sided or left-sided clots
16. Erroneous patient enrolment
17. Premature discontinuation of the ablation procedure
18. Inability to induce arrhythmia or lacking reproducible, clearly determined endpoint for Radio frequency catheter ablation (RFCA)

Date of first enrolment
01/03/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Poland

Study participating centre
Obroncow Tobruku 19/92
Warsaw
Poland
01-474

Sponsor information

Organisation
ElMedica (Poland)

Sponsor details
Mieszka I 61
Kielce
Poland
25-624

Sponsor type
Industry

Website
http://www.elmedica.pl/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Poland)

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