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Comparing conventional verses contact force and electrical coupling index in atrial flutter ablation

Submission date 14/01/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/01/2015	**Overall study status** Completed	
Last Edited 09/02/2023	**Condition category** 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
17567

Study information

Scientific Title
Randomised trial comparing conventional versus contact force and electrical coupling index in atrial flutter ablation (VERISMART TRIAL)

Acronym
VERISMART TRIAL

Study objectives
Catheter ablation is now routinely used in the management of heart rhythm disorders. One of the problems with the approach is that it has not been possible to determine whether the ablation catheter is in direct contact with the heart tissue or not. This is important because too much contact has safety implications and too little means that the therapy will be ineffective. Recently two different technologies have been developed to determine contact. Currently it is not known if one is superior to the other, and the objective of this trial is to determine whether there is a difference when treating a rhythm called atrial flutter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/YH/0038

Study design
Randomised; Interventional

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Arrhythmia

Interventions
CF versus ECI in CTI flutter

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Time to bidirectional block

Secondary outcome measures
N/A

Overall study start date
01/02/2015

Completion date
01/02/2017

Eligibility

Key inclusion criteria
1. Age =18 years
2. Documented paroxysmal or persistent atrial flutter

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment
114

Key exclusion criteria
1. Inability or unwillingness to receive oral anticoagulation
2. Previous ablation procedure for AFL
3. Unwillingness or inability to complete the required follow up arrangements
4. Concomitant atrial fibrillation

Date of first enrolment
01/02/2015

Date of final enrolment

01/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds General Infirmary
Great George Street
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

Sponsor details
Research & Development
34 Hyde Terrace
Leeds
England
United Kingdom
LS2 9LN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
Biosense Webster Inc (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		03/04/2019	10/05/2021	Yes	No
Protocol (other)			09/02/2023	No	No
HRA research summary			28/06/2023	No	No