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Isoprenaline infusion as a method of induction of atrial fibrillation

Submission date	Recruitment status	[_] Prospectively registered
08/01/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/02/2024	Circulatory System	

Plain English summary of protocol
Plain English summary under review

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2014-002290-11

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
18091

Study information

Scientific Title
Isoprenaline infusion as a method of induction of Atrial Fibrillation: a randomised controlled trial investigating the use of Isoprenaline to induce an episode of atrial fibrillation

Acronym
IsoAF study

Study objectives
This study will investigate a use for a well-established drug called isoprenaline. Some doctors use an intravenous infusion of isoprenaline to cause patients to go into an abnormal heart rhythm called atrial fibrillation. This use is part of a procedure to treat that abnormal rhythm. Although it is reasonable to suppose that isoprenaline will have this effect, its ability to induce atrial fibrillation has never been definitively proven. Using a double blinded, placebo controlled design our study will demonstrate the efficacy of induction of atrial fibrillation using an isoprenaline infusion. In addition, the data collected from this trial will demonstrate whether this effect is consistent in the same subject on different occasions and will characterise the ability of isoprenaline to induce atrial fibrillation in different patient groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/SC/1171

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 the 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

Isoprenaline

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Isoprenaline

Primary outcome measure
Presence or absence of atrial fibrillation

Secondary outcome measures
N/A

Overall study start date
05/01/2015

Completion date
31/12/2015

Eligibility

Key inclusion criteria
All participants in all groups:
1. The participant must be willing to comply with the protocol requirements including travelling to the investigating hospital for the attendances required for the study
2. Provision of informed consent
3. Participants must be over 18 years of age

Group 1 – Paroxysmal Atrial Fibrillation Group
1. Participants must have a history of arrhythmia with 12 lead ECG or ambulatory ECG monitoring recordings documenting a diagnosis of atrial fibrillation
2. Participants must have a pattern of symptoms and investigation results consistent with a diagnosis of paroxysmal atrial fibrillation

Group 2 – SVT Ablation Group
1. Participants must have a history of arrhythmia with documented regular, narrow complex tachycardia available on either 12 lead ECG or ambulatory ECG monitor recording
2. Participants must be listed to undergo an Electrophysiology study with a view to performing an ablation procedure
3. Participants must go on to have an ablation procedure for either AtrioVentricular Reentrant Tachycardia (AVRT) or AtrioVentricular Nodal Reentrant Tachycardia (AVNRT) with a defined procedural endpoint

Group 3 – Atrial Flutter Ablation Group
1. Participants must have a history of arrhythmia with 12 lead ECG documentation fulfilling prespecified criteria for diagnosis of common type (cavotricuspid isthmus dependent) atrial flutter

2. Participants must be listed to undergo a cavotricuspid isthmus ablation for common type atrial flutter
3. Participants must go on to have only a cavotricuspid isthmus ablation for common type atrial flutter
4. Sustained bidirectional cavotricuspid isthmus block must have been demonstrated as the endpoint for the ablation procedure

Group 4 – Pulmonary Vein Isolation Group
1. Participants must have a history of arrhythmia with 12 lead ECG or ambulatory ECG monitoring recordings documenting a diagnosis of atrial fibrillation
2. Participants must be listed to undergo an ablation procedure for atrial fibrillation with the intent of the attending physician to perform pulmonary vein isolation alone as an ablation strategy
3. Participants must be in sinus rhythm at the time that they enter the Cardiac Electrophysiology Laboratory for their
ablation procedure.
4. Participants must have an ablation procedure for atrial fibrillation and this must have involved only ablation to achieve pulmonary vein isolation
5. Pulmonary vein isolation must have been demonstrated as the endpoint for the ablation procedure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 235; UK Sample Size: 235

Key exclusion criteria
All participants in all groups:
1. Allergy to Isoprenaline
2. Any treatment with Amiodarone in the 3 months prior to ablation procedure
3. Hypertrophic cardiomyopathy
4. Suspected acute myocarditis
5. Uncorrected, severe valvulopathy graded by transthoracic echocardiographic parameters
6. An Acute Coronary Syndrome within the last 6 months
7. Recent (within the last 6 months) or scheduled coronary revascularisation
8. Ongoing angina symptoms without investigations demonstrating the absence of myocardial ischaemia
9. Left ventricular ejection fraction measured at <30%
10. Symptoms of decompensated heart failure syndrome in the last 3 months
11. Severe obstructive lung disease
12. Pregnancy at the time of enrolment or a desire to become pregnant during the study period

13. Reduced life expectancy not associated with cardiovascular disease (less than 1 year)
14. Unable to provide informed consent

Group 1 – Paroxysmal Atrial Fibrillation Group
15. Any past history of episode of persistent atrial fibrillation at the time of enrolment to the study
16. Treatment with any antiarrhythmic agent within six halflives of that agent from before an administration of the study drug infusion

Group 2 – SVT Ablation Group
1. Any past history of atrial fibrillation documented on 12 lead ECG or ambulatory ECG monitor
2. Any past history of atrial flutter documented on 12 lead ECG or ambulatory ECG monitor
3. Characterisation of SVT as any arrhythmia other than ANRT or AVNRT
4. Treatment with any antiarrhythmic agent within six halflives of that agent from the ablation procedure (including intraprocedural use) with the exception of isoprenaline and adenosine

Group 3 – Atrial Flutter Ablation Group
1. Characterisation of arrhythmia as any arrhythmia other than cavotricuspid isthmus dependent atrial flutter at the time of ablation
2. Treatment with any antiarrhythmic agent within six halflives of that agent from the ablation procedure (including intraprocedural use) with the exception of isoprenaline and adenosine

Group 4 – Pulmonary Vein Isolation Group
1. Requirement for a more extensive ablation strategy than pulmonary vein isolation alone
2. Intraprocedural treatment with any antiarrhythmic agent with the exception of isoprenaline and adenosine
3. Treatment with any antiarrhythmic agent in the days before the ablation within six halflives of that agent from the ablation procedure

Date of first enrolment
05/01/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Bournemouth Hospital
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Sponsor information

Organisation
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03xqffv86

Funder(s)

Funder type
Government

Funder Name
Bournemouth Cardiac Research Fund

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?
Protocol file	version 4.0	09/09/2014	28/04/2023	No	No
Basic results			16/02/2024	No	No
Other files	Statement from sponsor regarding data quality		16/02/2024	No	No