Dual Versus Single Shock for Cardioversion of Atrial Fibrillation

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03943693	ACTIVE, NOT RECRUITING	MAY 9, 2019	APRIL 24, 2020

STUDY DESCRIPTION

Brief Summary

The investigators aim to investigate the immediate success rate (rate of termination of atrial fibrillation) of dual shock cardioversion compared with standard single shock cardioversion in patients with baseline characteristics adversely influencing successful cardioversion. Baseline characteristics known to reduce the success rate of single shock cardioversion include: increased body mass index (BMI), chronic obstructive pulmonary disease, sleep apnea, enlarged left atrium, longer duration of atrial fibrillation and use of amiodarone.

Condition or Disease: Atrial Fibrillation

Intervention/treatment: Device: Double shock
Device: Single shock

Phase: Phase 4

DETAILED DESCRIPTION

Patient Enrollment Patient enrollment will be open enrollment to inpatient/outpatients who meet the inclusion/exclusion criteria listed above. This is a double-blinded study with randomization to dual shock or standard single shock synchronized cardioversion for patients requiring cardioversion for atrial fibrillation. Randomization will be performed using a standard computer-based randomization system.
Cardioversion will be performed with Zoll R series Defibrillator, which was approved by the FDA in 2017 for use as a defibrillator, with a 510K approval for use in cardioversion of atrial arrhythmias. After obtaining consent, before sedation is administered, all patients will have 2 pads placed in the antero-posterior pad position on the left chest (guideline recommended position for cardioversion of atrial fibrillation) and an additional 2 pads placed in the standard Ventricular Tachycardia/Advanced Cardiac Life Support positions, where the anterior pad is centered over the right infraclavicular space and the apical pad is placed over the left axilla . All patients will be sedated using propofol administered by anesthesiology or a combination of fentanyl and midazolam administered by cardiology staff.
Patients randomized to single shock will then be treated initially with a 200 Joule shock through the antero-posterior pads only. A repeat attempt will be made using the same approach if the initial shock fails. If the second attempt fails, the single shock approach will be considered to have failed. Patients will be crossed over to dual shock therapy while under the same sedation episode. For cross-over patients, two near-simultaneous 200-Joule shocks will be delivered through the two sets of pads already in position. If this fails further treatment will be determined by the primary team/attending cardiologist.
Patients randomized to the dual shock group will have two near-simultaneous 200-Joule shocks delivered through the two sets of pads (antero-posterior position and right infraclavicular-axillary position). The first of these shocks will be synchronized. If the first attempt with this approach fails to terminate atrial fibrillation a second attempt will be made using the same approach. If the second attempt fails the dual shock approach will be considered to have failed and further treatment will be determined by the primary team/attending cardiologist.
Primary Endpoint - Successful termination of atrial fibrillation after initial Direct Current Ccardioversion (DCCV). Successful cardioversion = immediate termination of atrial fibrillation with electrocardiographic (ECG) evidence of atrial fibrillation (AF) termination. The physician deciding whether AF was successfully terminated will be blinded to whether the shock was with single or dual shocks. - Partial success will be considered if atrial fibrillation is terminated by the second attempt using the same approach. Secondary Endpoints - Maintenance of normal sinus rhythm at one hour post cardioversion - Presence of symptomatic skin burn (symptoms rated on a scale of 1-10) - Thromboembolic complications - Ventricular Arrhythmias requiring additional shock therapy Documentation of Anticoagulation
All patients need to have established therapeutic anticoagulation. Either 1) Therapeutic warfarin (with International normalized ratio (INR) >2) or therapeutic doses of apixaban, dabigatran, rivaroxaban or edoxaban for at least 3 consecutive weeks before and with plans to continue 4 weeks after cardioversion. 2) Therapeutic anticoagulation with intravenous heparin or therapeutic subcutaneous enoxaparin or non-vitamin K oral anticoagulant if atrial fibrillation episode is known to be of recent onset (<48 hours), with anticoagulation to continue for at least one week post cardioversion. 3) Sub-therapeutic or no anticoagulation preceding cardioversion, but transesophageal echocardiogram (TEE) confirming absence of intra-cardiac thrombus. Therapeutic anticoagulation should be administered just prior to cardioversion and planned to continue for at least 4 weeks post cardioversion.

STUDY DESIGN

Study Type:	Interventional
Estimated Enrollment :	100 participants
Intervention Model :	Parallel Assignment
Masking:	Double (Participant, Care Provider)
Primary Purpose:	Treatment
Official Title:	Dual Shock Versus Single Shock Synchronized External Direct Current Cardioversion for Atrial Fibrillation - A Double-blinded Randomized Trial

Actual Study Start Date:	April 2019
Estimated Primary Completion Date:	December 2021
Estimated Study Completion Date:	December 2021

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Active Comparator: Double Shock Group Patients randomized to the dual shock group will have two near-simultaneous 200-Joule shocks delivered through the two sets of pads (antero-posterior position and right infraclavicular-axillary position). The first of these shocks will be synchronized.	Device: Double shock Patients randomized to the dual shock group will have two near-simultaneous 200-Joule shocks delivered through the two sets of pads (antero-posterior position and right infraclavicular-axillary position). The first of these shocks will be synchronized. If the first attempt with this approach fails to terminate atrial fibrillation a second attempt will be made using the same approach. If the second attempt fails the dual shock approach will be considered to have failed and further treatment will be determined by the primary team/attending cardiologist.
Active Comparator: Single Shock Group Patients randomized to single shock will then be treated initially with a 200 Joule shock through the antero-posterior pads only.	Device: Single shock Patients randomized to single shock will then be treated initially with a 200 Joule shock through the antero-posterior pads only. A repeat attempt will be made using the same approach if the initial shock fails. If the second attempt fails, the single shock approach will be considered to have failed. Patients will be crossed over to dual shock therapy while under the same sedation episode. For cross-over patients, two near-simultaneous 200-Joule shocks will be delivered through the two sets of pads already in position. If this fails further treatment will be determined by the primary team/attending cardiologist.

OUTCOME MEASURES

Primary Outcome Measures: 1. Cardioversion to sinus rhythm [Time Frame: Immediately following cardioversion]
Successful termination of atrial fibrillation after initial DCCV. Successful = cardioversion = immediate termination of atrial fibrillation

Secondary Outcome Measures:
1. Maintenance of normal sinus rhythm at one hour post cardioversion [Time Frame: Within 24 hours]

2. Presence of symptomatic skin burn [Time Frame: Immediately following cardioversion]
Symptoms rated on a scale 1-10
3. Thromboembolic complications [Time Frame: Within 24 hours]
4. Ventricular arrhythmias requiring additional shock therapy [Time Frame: Immediately following cardioversion]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 80 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Outpatient or inpatients with atrial fibrillation sent for elective direct current cardioversion (DCCV) with at least 1 of the following risk factors will be included:
- BMI >30
- History of Chronic Obstructive Pulmonary Disease/emphysema/asthma
- Significant Valvular heart disease (at least moderate regurgitation/stenosis)
- History of Heart Failure with preserved Ejection Fraction/Heart Failure with reduced Ejection Fraction
- Cardiomyopathy with ejection fraction 4.5cm
- Presence of Left ventricular hypertrophy (≥1.1cm septal/posterior wall M-mode) on transthoracic echocardiogram
- History of sleep apnea

Exclusion Criteria:
- Consent not obtained
- 80 y.o.
- Not adequately anti-coagulated
- Patient hemodynamically unstable and DCCV required as an emergent procedure
- Prisoners or pregnant patients

CONTACTS AND LOCATIONS

Contacts

Locations

United States, Oklahoma	University of Oklahoma Health Science Center	Oklahoma City

Sponsors and Collaborators

University of Oklahoma

Investigator

Principal Investigator : Deborah Lockwood, MD University of Oklahoma

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MORE INFORMATION

Publications of Results	Chugh SS, Havmoeller R, Narayanan K, Singh D, Rienstra M, Benjamin EJ, Gillum RF, Kim YH, McAnulty JH Jr, Zheng ZJ, Forouzanfar MH, Naghavi M, Mensah GA, Ezzati M, Murray CJ. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. Circulation. 2014 Feb 25;129(8):837-47. doi: 10.1161/CIRCULATIONAHA.113.005119. Epub 2013 Dec 17. Boriani G, Diemberger I, Biffi M, Domenichini G, Martignani C, Valzania C, Branzi A. Electrical cardioversion for persistent atrial fibrillation or atrial flutter in clinical practice: predictors of long-term outcome. Int J Clin Pract. 2007 May;61(5):748-56. Larsen MT, Lyngborg K, Pedersen F, Corell P. [Predictive factors of maintenance of sinus rhythm after direct current (DC) cardioversion of atrial fibrillation/atrial flutter]. Ugeskr Laeger. 2005 Sep 5;167(36):3408-12. Danish. Viñolas X, Freire F, Romero-Menor C, Alegret JM. [Predictors of reversion to sinus rhythm previous to electrical cardioversion in patients with persistent atrial fibrillation treated with anti-arrhythmic drugs]. Med Clin (Barc). 2013 Apr 20;140(8):351-5. doi: 10.1016/j.medcli.2012.02.026. Epub 2012 Sep 14. Spanish. Marrouche NF, Bardy GH, Frielitz HJ, Günther J, Brachmann J. Quadruple pads approach for external cardioversion of atrial fibrillation. Pacing Clin Electrophysiol. 2001 Sep;24(9 Pt 1):1321-4.
Other Publications	Saliba W, Juratli N, Chung MK, Niebauer MJ, Erdogan O, Trohman R, Wilkoff BL, Augostini R, Mowrey KA, Nadzam GR, Tchou PJ. Higher energy synchronized external direct current cardioversion for refractory atrial fibrillation. J Am Coll Cardiol. 1999 Dec;34(7):2031-4.
Responsible Party :	University of Oklahoma
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Other Study ID Numbers :	10276
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Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	Yes
Product Manufactured in and Exported from the U.S.:	Yes
Keywords provided by University of Oklahoma:	*Cardioversion*
Additional relevant MeSH terms :	*Atrial Fibrillation*