Effect of Remote Ischemic Preconditioning on Incidence of Atrial Fibrillation in Patients Undergoing Coronary Artery Bypass Graft Surgery

The recruitment status of this study is unknown because the information has not been verified recently.

Verified July 2013 by Baystate Medical Center.
Recruitment status was Recruiting

Sponsor:
Baystate Medical Center

Information provided by (Responsible Party):
Amir Lotfi, MD, Baystate Medical Center

ClinicalTrials.gov Identifier:
NCT01500369

First received: December 22, 2011
Last updated: July 2, 2013
Last verified: July 2013
History of Changes

Purpose

Atrial fibrillation is the most common arrhythmic complication after coronary artery bypass grafting (CABG). Post operative atrial fibrillation (POAF) increases morbidity and mortality. Inflammation could be a factor in POAF and recent evidence of remotely inducing ischemia may reduce inflammation and cardiac injury. The investigators plan to use a blood pressure cuff on the arm as a method to produce remote ischemia and assess the occurrence of POAF for seven day.

Condition	Intervention	Phase
Atrial Fibrillation	Other: sphygmomanometer cuff inflations Other: standard of care	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Subject)
Primary Purpose: Prevention

Official Title: Effect of Remote Ischemic Preconditioning on Incidence of Atrial Fibrillation in Patients Undergoing Coronary Artery Bypass Graft Surgery A Randomized Controlled Trial

Resource links provided by NLM:

Genetics Home Reference related topics: familial atrial fibrillation

MedlinePlus related topics: Atrial Fibrillation Coronary Artery Bypass Surgery

Genetic and Rare Diseases Information Center resources: Familial Atrial Fibrillation

U.S. FDA Resources

Further study details as provided by Baystate Medical Center:

Primary Outcome Measures:

- Post op atrial fibrillation [Time Frame: 7 days post cardiac surgery] [Designated as safety issue: No]

  Assess the indicence of post operative atrial fibrillation

Secondary Outcome Measures:

- Stroke [Time Frame: 7 days] [Designated as safety issue: Yes]

  Post operative stroke

Estimated Enrollment:	410
Study Start Date:	December 2010
Estimated Study Completion Date:	June 2015
Estimated Primary Completion Date:	December 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: remote ischemic conditiong Patients in the treatment group will receive three sequential sphygmomanometer cuff inflations on their right upper arm after induction of anesthesia in the operating room. The cuff will be inflated by the OR nurse up to 200 mmHg for five minutes each occasion, with five minutes deflation in between inflations. Following this "pre-conditioning" phase, routine anesthesia procedures will be implemented. The entire pre-conditioning phase will last 30 minutes.	Other: sphygmomanometer cuff inflations : Patients in the treatment group will receive three sequential sphygmomanometer cuff inflations on their right upper arm after induction of anesthesia in the operating room. The cuff will be inflated by the OR nurse up to 200 mmHg for five minutes each occasion, with five minutes deflation in between inflations. Following this "pre-conditioning" phase, routine anesthesia procedures will be implemented. The entire pre-conditioning phase will last 30 minutes.
Placebo Comparator: Standard Care Patients in the control group will have the sphygmomanometer cuff placed on their right upper arm, but the cuff will not be inflated. Similar to patients in the treatment group, patients in the control group will undergo the same 30 minute delay before induction of anesthesia and surgery	Other: standard of care Placebo Comparator

Show Detailed Description

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- This will be a prospective randomized controlled study on patients older than 18 years old who are undergoing elective CABG with or without valve surgery.

Exclusion Criteria:

- any preoperative rhythm other than sinus,
- history of atrial fibrillation,
- New York Hear Association (NYHA) IV congestive heart failure,
- cardiogenic shock,
- emergent CABG and/or valve surgery,
- bleeding diathesis, and
- women of child-bearing potential. Eligible patients will participate after obtaining consent.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT01500369

Contacts

Contact: Amir Lotfi, MD 413 7934 4490 amir.lotfi@bhs.org

Locations

United States, Massachusetts

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Sponsors and Collaborators

Baystate Medical Center

Investigators

Principal Investigator: amir Lotfi, MD Baystate Medical Center

More Information

Responsible Party:	Amir Lotfi, MD, MD, Baystate Medical Center
ClinicalTrials.gov Identifier:	NCT01500369 History of Changes
Other Study ID Numbers:	Unique Protocol ID
Study First Received:	December 22, 2011
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Health Authority:	United States: Institutional Review Board

Keywords provided by Baystate Medical Center:
atrial fibrillation
remote ischemic conditioning

Additional relevant MeSH terms:
Atrial Fibrillation
Arrhythmias, Cardiac
Cardiovascular Diseases
Heart Diseases
Pathologic Processes

ClinicalTrials.gov processed this record on April 22, 2016