Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of cardioplegic solutions which contain lidocaine or procaine hydrochloride in cognitive function after CABG surgery

Protocol summary

Summary

The aim of this randomized double-blind clinical trial is to comparison of cardioplegic solutions which contain lidocaine or procaine hydrochloride in cognitive function after CABG procedure in Mazandaran Heart Center. A total of 110 patients, meeting eligibility criteria, are randomly allocated into two equal groups. Inclusion criterias are informed written consent; Elective CABG surgery; Age between 20 and 70 years; Use of the cardiopulmonary pump during surgery. Exclusion criterias are history of symptomatic cerebrovascular disease; Alcohol use (> 50 cc /day); History of psychiatric illness (any clinical diagnosis requiring therapy); History of drug abuse (any illicit drug abuse in the past 3 months); Hepatic insufficiency (liver function tests > 1.5 times of the normal upper limit); Sever pulmonary insufficiency (requiring home oxygen therapy); Renal failure (baseline serum creatinine > 2mg/dl); Lack of cooperation in response to cognitive test; together with other cardiac surgery (valvular surgery); History of previous cardiac surgery; Ejection fraction < 35%; history of sensitivity to lidocaine or procaine hydrochloride. After connecting the patients to cardiopulmonary pump, for inducing of cardiac arrest, in the control group cardioplegic solution with 5 mg/kg procaine hydrochloride and in the intervention group cardioplegic solution with 2 mg/kg lidocaine are used. Cognitive function test will be done by The Folstein Mini Mental exam the day before, 10 days and 2 months after operation. Assessments perform individually by an experienced psychometrician who was blinded to treatment group. Also, just before operation, 10 and 60 minutes after connecting the patients to cardiopulmonary pump, 5cc arterial blood was taken to determine blood levels of lidocaine.

General information

Acronym

CABG= Coronary Artery Bypass Graft

IRCT registration information

IRCT registration number: **IRCT20110424365N8**
Registration date: **2011-06-28, 1390/04/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-06-28, 1390/04/07

Registrant information

Name

Afshin Gholipour Baradari

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2011-06-15, 1390/03/25

Expected recruitment end date

2011-08-16, 1390/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cardioplegic solutions which contain lidocaine or procaine hydrochloride in cognitive function after CABG surgery

Public title
Cognitive deficit in first time CABG patients receiving Lidocaine versus procaine hydrochloride as an additive to the cardioplegia solution
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Informed written consent; Elective CABG surgery; Age between 20 and 70 years; Use of the cardiopulmonary pump during surgery. Exclusion criteria: History of symptomatic cerebrovascular disease; Alcohol use (> 50 cc /day); History of psychiatric illness (any clinical diagnosis requiring therapy); History of drug abuse (any illicit drug abuse in the past 3 months); Hepatic insufficiency (liver function tests > 1.5 times of the normal upper limit); Sever pulmonary insufficiency (requiring home oxygen therapy); Renal failure (baseline serum creatinine > 2mg/dl); Lack of cooperation in response to cognitive test; together with other cardiac surgery (valvular surgery); History of previous cardiac surgery; Ejection fraction < 35%; history of sensitivity to lidocaine or procaine hydrochloride.
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Mazandaran University of Medical Sciences
Street address
Moallem Square, Mazandaran University of Medical Sciences
City
Sari
Postal code
46175866
Approval date
2011-06-15, 1390/03/25
Ethics committee reference number
90-64

Health conditions studied

1

Description of health condition studied
Cognitive function after CABG surgery
ICD-10 code
F54
ICD-10 code description
Psychological and behavioural factors associated with disorders or diseases classified elsewhere

Primary outcomes

1

Description
Cognitive function
Timepoint
The day before, 10 days and 2 month after operation
Method of measurement
Folstein Neurocognitive Test

Secondary outcomes

1

Description
Cardiac Dysrrhythmia
Timepoint
Before trial, during the operation and three days later
Method of measurement
Cardiac monitoring

2

Description
Serum lidocaine level
Timepoint
10 min before CPB, 10 and 60 min after CPB
Method of measurement
Laboratory kit

Intervention groups

1

Description
Intervention group receive lidocaine 2 mg/kg in cardioplegia solution
Category

Treatment - Drugs

2

Description
Control group receive procaine hydrochloride 5 mg/kg in cardioplegia solution
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mazandaran Heart center
Full name of responsible person
Afshin Gholipour Baradari
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Artesh Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati MD
Street address
Moallem Square, Mazandaran university of medical sciences, Sari, Iran
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Mazandaran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty