Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

The Evaluation of the effect of preoperative(spinal Anesthesia) Atropine administration on maternal hemodynamics and PH of neonatal umbilical cord blood in parturients undergoing cesarean section under spinal anesthesia

Protocol summary

Study aim

The Evaluation of the effect of preoperative (spinal anesthesia) Atropine administration on maternal hemodynamics and neonatal umbilical cord blood PH in parturients undergoing cesarean section under spinal anesthesia

Design

This randomized double blinded clinical trial includes 2 case and control groups. Randomization will be performed by using a random number table that divides the patients into two-40 patients group(total 80 patients) and allocates a code to each person and group. This study will be performed in phase 4.

Settings and conduct

This study will be conducted in Imam Khomeini Hospital Complex. After randomization, using convenient and consequent sampling, the patients that are candidates for the elective cesarean section will receive a single dose of atropine(10 microgram/kg) or placebo, and they will undergo spinal anesthesia. Afterward, maternal hemodynamic parameters including heart rate, blood pressure and Ph of the neonatal umbilical cord blood sample would be tested and registered.

Participants/Inclusion and exclusion criteria

All parturients who are between 18 to 45 years old and are candidates for performing elective cesarian section under spinal anesthesia.

Intervention groups

All healthy parturients who are between 18 to 45 years old and are candidates for performing elective cesarean section under spinal anesthesia will be randomly categorized into two groups including intervention and placebo group using random number table. In the first group we will administer Atropine at maximum dose of 0.6 mg and normal saline will be administered to the second group as placebo at equivalent volume

Main outcome variables

maternal hemodynamic parameters; Ph of the neonatal umbilical cord blood sample; the amount of medications used

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160208026447N2**
Registration date: **2021-04-07, 1400/01/18**
Registration timing: **retrospective**

Last update: **2021-04-07, 1400/01/18**
Update count: **0**

Registration date

2021-04-07, 1400/01/18

Registrant information

Name
Amirhossein Orandi
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6119 2828
Email address
horandi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date
2017-03-19, 1395/12/29
Actual recruitment start date
2016-03-20, 1395/01/01
Actual recruitment end date
2017-05-21, 1396/02/31
Trial completion date
2017-05-22, 1396/03/01

Scientific title
The Evaluation of the effect of preoperative(spinal Anesthesia) Atropine administration on maternal hemodynamics and PH of neonatal umbilical cord blood in parturients undergoing cesarean section under spinal anesthesia

Public title
The Evaluation of the effect of Atropine administration on parturients' hemodynamics undergoing cesarean section under spinal anesthesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant females 18 to 45 years old undergoing cesarean section under spinal anesthesia Pregnant females without cardiac or other systemic diseases Pregnant females who have filled written informed consent to perform spinal anesthesia
Exclusion criteria:
disagreement in participating in study any history of cardiac diseases
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
4
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial, two groups, including intervention group (I) and placebo (P), were randomly assigned based on a table of even and odd random numbers (including a chain of 80 numbers) designed by a statistical consultant. At the time of the patient's entry into the operating room, based on the sequence of the even and odd random number chain, if it was an even number, the envelope containing a prepared atropine syringe delivered to the injector, and if it was an odd number, the envelope containing prepared normal saline delivered to the injector.
Blinding (investigator's opinion)
Double blinded
Blinding description
Drugs and placebo are prepared in similar envelopes. Each drug envelope is given a code. Each patient is given a code as well. Patients receive an envelope in order of arrival. This envelope is returned on the day of surgery by an unrelated person. Only the analyzer knows which drug and patient belong to which group. Researchers and patients are unaware of the type of code and the content of the codes
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences- Imam Khomeini Hospital Complex
Street address
keshavarz boulvard- Imam Khomeini Hospital Complex
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2017-04-21, 1396/02/01
Ethics committee reference number
TUMS.IKHC.REC.1396.4446

Health conditions studied

1

Description of health condition studied
Hemodynamic changes after spinal anesthesia in elective cesarean section
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
maternal hemodynamic parameters
Timepoint
After administering Atropine as premedication or normal saline as a placebo the maternal vital signs would be

checked and recorded, thereafter spinal anesthesia will be provided, and after repositioning to the supine position the vital signs would be checked instantly and would be repeatedly checked every 3 minutes. After delivery, the Ph of neonatal umbilical cord blood sample would be checked instantly and will be recorded.

Method of measurement

Vital signs monitoring system

2

Description

Ph of umbilical cord blood sample

Timepoint

After administering Atropine as premedication or normal saline as a placebo the maternal vital signs would be checked and recorded, thereafter spinal anesthesia will be provided, and after repositioning to the supine position the vital signs would be checked instantly and would be repeatedly checked every 3 minutes. After delivery, the Ph of neonatal umbilical cord blood sample would be checked instantly and will be recorded.

Method of measurement

Using Blood Gas Analysis

Secondary outcomes

1

Description

The number of drugs used during surgery

Timepoint

At the end of surgery

Method of measurement

the number of drugs used at the end of procedure

Intervention groups

1

Description

Intervention group: Administration of 10 microgram/kg atropine intravenously prior to performing spinal anesthesia.

Category

Prevention

2

Description

Control group: administration of normal saline in equivalent volume of drug used in case group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Dr.Amirhossein Orandi

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2828

Email

horandi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amirhossein Orandi

Street address

Keshavarz Blvd-Imam Khomeini hospital Complex-department of Anesthesiology

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2828

Email

horandi@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amirhossein Orandi

Position
Assistant professor of department of anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Keshavarz Blvd- Imam Khomeini Hospital Complex

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2828

Email
horandi@sina.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr.Amirhossein Orandi

Position
Anesthesiologist

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Imam Khomeini hospital, end of Keshavarz Blvd, Tehran

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2828

Fax

Email
horandi@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr.Amirhossein Orandi

Position
Anesthesiologist

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Imam Khomeini hospital, end of Keshavarz Blvd, Tehran

City
Tehran

Province
Tehran

Postal code
1419733141

Phone
+98 21 6119 2828

Fax

Email
horandi@sina.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The results of the study will be published without any name.

When the data will become available and for how long
1year

To whom data/document is available
The researcher and his supervisor (professor)

Under which criteria data/document could be used
In order to publish in medical journals, without any name of participants.

From where data/document is obtainable
researcher and supervisor(professor)

What processes are involved for a request to access data/document
sending an appropriate written request to the supervisor

Comments