

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of Efficacy of intravenous Atropine in prevention of post spinal hypotension and bradycardia in cesarean section.

Protocol summary

Study aim

Evaluation of Efficacy of intravenous Atropine in prevention of post spinal hypotension and bradycardia in cesarean section.

Design

The aim of this study was to evaluate the effect of venous atropine on the prevention of hypotension and bradycardia following spinal anesthesia in cesarean section. In this double blind study, 88 patients aged 18 to 46 years with cesarean delivery at Fatemeh Hospital of Hamadan will be treated in one of two groups after receiving informed consent. In one group, 0.5 mg intravenous atropine was administered and in the other group 1 ml normal saline was prepared in the same syringes prepared by the anesthetist nurse according to the predetermined list and immediately injected intraperitoneally after spinal anesthesia. Patients who declare that they are not collaborating or have sensitivity to medications used. will be excluded.

Settings and conduct

Fatemeh Hospital of Hamadan

Participants/Inclusion and exclusion criteria

Satisfaction to participate in the project; Pregnant women aged 18 to 46; Pregnant women who underwent cesarean section under spinal anesthesia

Intervention groups

In one group, 0.5 mg intravenous atropine was administered and in the other group 1 ml normal saline was prepared in the same syringes prepared by the anesthetist nurse according to the predetermined list and immediately injected intraperitoneally after spinal anesthesia.

Main outcome variables

Hypotension and bradycardia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N18**

Registration date: **2019-05-17, 1398/02/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-17, 1398/02/27**

Update count: **0**

Registration date

2019-05-17, 1398/02/27

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

manouchehrian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-15, 1398/02/25

Expected recruitment end date

2020-05-14, 1399/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Efficacy of intravenous Atropine in prevention of post spinal hypotension and bradycardia in cesarean section.

Public title

Efficacy of intravenous Atropine in prevention of post spinal hypotension and bradycardia in cesarean section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the project Pregnant women aged 18 to 46 Pregnant women who underwent cesarean section under spinal anesthesia

Exclusion criteria:

sensitivity to medications used Patients who have failed spinal anesthesia and undergo general anesthesia Lung disease, heart disease, asthma, fever, hypertension, preeclampsia and eclampsia, cardiac arrhythmia Multiple pregnancies HR resting more than 100 in minutes, Beta-blocker intake

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study , a randomized block design with four replications is used. we provide four paper sheets . We write two letters A and on two other sheets of letter B. We mix the papers together and put them in the drawer of the table. With each of the qualified patients, one of the papers is taken out randomly and will be assigned to one of the two Atropine 0.5 mg or 1 ml of normal saline groups, depending on whether the drawn sheet is either A or B. After the random drawn out of four sheets, all the papers will be returned to the drawer and again the above procedure will continue for the next four patients until it reaches the sample volume.

Blinding (investigator's opinion)

Double blinded

Blinding description

In both groups A and B, medications will be prescribed two minutes before the extubation of the chip. In order to prevent the medication being detectable for patients and investigators, they are prepared and injected into syringes of the same size and shape and on the adhesives A and B by the anesthetist. Since drugs are prescribed and prescribed by an anesthetist, the clinician will not be aware of the type of prescribed medication that will measure and record the outcome of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan university of Medical Science

Street address

Fahmide Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.UMSHA.REC.1397.974

Health conditions studied

1

Description of health condition studied

Spinal anesthesia in cesarean section

ICD-10 code

Z38.01

ICD-10 code description

Single liveborn infant, delivered by cesarean

Primary outcomes

1

Description

hypotension

Timepoint

Every two minutes to 10 minutes, then every 5 minutes to 15 minutes, then every 10 minutes until the end of the surgery

Method of measurement

Non-invasive blood pressure

2

Description

bradycardia

Timepoint

Every two minutes to 10 minutes, then every 5 minutes to 15 minutes, then every 10 minutes until the end of the surgery

Method of measurement

Pulse Oximetry

Secondary outcomes

1

Description

Nausea & vomiting

Timepoint

after delivery

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: 0.5 mg of atropine is injected intravenously after spinal anesthesia

Category

Treatment - Drugs

2

Description

Control group: 1 ml of normal saline is injected intravenously immediately after spinal anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences

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Fatemieh Hospital, Pasdaran Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Associate professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nahid Manouchehrian

Position

Associate Professor of Hamadan University of Medical Sciences

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Associate Professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work