

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The Effect of glucose-containing fluids on Hemodynamic changes after Spinal Anesthesia for cesarean section

Protocol summary

Study aim

Determining the effect of prescribing fluids containing sugar on blood pressure and heart rate of a mother undergoing cesarean section

Design

Randomized clinical trial using closed-door envelope with control group, with parallel groups, double-blind, phase 3-2 on 60 patients

Settings and conduct

This study will be performed on pregnant women who are candidates for cesarean section (more than 37 weeks) who referred to Ghaem Hospital in Mashhad. The study was double-blind and participants and outcome analyzers would not know how to group.

Participants/Inclusion and exclusion criteria

Monozygotic and full-term pregnancies that are candidates for cesarean section and no diabetes and cardiovascular disease and no fetal abnormalities

Intervention groups

In this study, Full term pregnant mothers who are candidates for cesarean section before performing spinal anesthesia in the control group as a placebo of getting intravenous normal saline and in the intervention group intravenous normal saline containing 1% glucose (10 g per 1000 cc) 5 to 7 cc is infused based on weight in 15 to 20 minutes

Main outcome variables

Blood pressure, Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220417054563N1**

Registration date: **2022-04-24, 1401/02/04**

Registration timing: **prospective**

Last update: **2022-04-24, 1401/02/04**

Update count: **0**

Registration date

2022-04-24, 1401/02/04

Registrant information

Name

Samira Saghravarian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3881 9284

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-23, 1401/03/02

Expected recruitment end date

2023-02-21, 1401/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of glucose-containing fluids on Hemodynamic changes after Spinal Anesthesia for cesarean section

Public title

The effect of sugary fluids on cesarean mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious consent to enter the study Monozygotic

pregnancy Cesarean section candidate
Exclusion criteria:
Diabetes Cardiovascular and cerebral disease Excessive bleeding and the need for blood transfusions

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with table of random numbers available at "www.randomization.com" website will be used. Numbers will be placed in sealed envelopes and each closed envelope is assigned to one participant placing them in one of the two groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The subjects and those evaluating the outcome will be unaware of the intervention and control groups. Written consent is obtained from patients, but at the same time patients do not know whether they are in the placebo or intervention group, the researcher evaluating the outcome does not know which group the patients are in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Science

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9117699199

Approval date

2022-02-05, 1400/11/16

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.021

Health conditions studied

1

Description of health condition studied

Term pregnant women who are candidates for cesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Blood pressure

Timepoint

During surgery (Before spinal; 5 and 10 minutes after spinal and end of operation)

Method of measurement

Automatic barometer

2

Description

Heart rate

Timepoint

During surgery (Before spinal; 5 and 10 minutes after spinal and end of operation)

Method of measurement

Electrocardiogram

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In this study, Full term pregnant mothers who are candidates for cesarean section, 5 to 7 cc of venous normal saline is infused in 15 to 20 minutes based on weight before spinal anesthesia.

Category

Placebo

2

Description

Intervention group: In this study, Full term pregnant mothers who are candidates for cesarean section, before performing spinal anesthesia, intravenous normal saline containing 1% glucose (10 g per 1000 cc) is infused 5 to 7 cc based on weight in 15 to 20 minutes.

Category

Rehabilitation

Country of origin**Type of organization providing the funding**

Academic

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem Hospital

Full name of responsible person

Masoomeh Tabari

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Ghaem Hospital, Ahmad Abad AVE

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Masoomeh Tabari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available