

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the effect of general and spinal anesthesia on serum level and gene expression of interleukin 4, 6, 10 and 17; TGF- β and IFN- γ in maternal and umbilical cord blood in elective cesarean section

Protocol summary

Study aim

Determining the effect of general and spinal anesthesia on serum level and gene expression of IL 4, 6, 10, 17, TGF- β and IFN- γ in maternal and umbilical cord blood in elective cesarean section

Design

Clinical trial with 2 parallel groups, single blind, randomised, 20 patients in each group

Settings and conduct

After entering women who are candidate for cesarean referred to Niknafs Hospital in Rafsanjan, An anesthesiologist will visit the patients. If there is no contraindication for SA or GA and none of the methods is preferred for the patient, the anesthesiologist will tell the patient about the research project. If the patient agrees to participate in the study, he will sign an informed consent form. Person who tests interleukin-assays, extracts RNA and synthesizes cDNA is blinded to the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 20 to 45, single pregnancy, term pregnancy and no complications such as chorioamnionitis and premature rupture of membrane. Exclusion criteria: unwanted pregnancy, a history of illness such as hypertension, diabetes, Cardiovascular disease, history of immunodeficiency diseases including HIV and hepatitis B, mental disorders, inflammatory diseases, drug use, smoking, alcohol and opium addiction

Intervention groups

Intervention group 1 (GA group): In this group induction of anesthesia will be performed using thiopental, 4-6 mg / kg sodium and succinylcholine, 1-1.5 mg /kg. Intervention group 2 (SA): spinal anesthesia will be performed through injection of 0.5 ml marcaine (0.5% produced by AstraZeneca, Sweden) in the sub-arachnoid space using a quincke needle (produced in Japan), at the

L3-L4 level in the sitting position.

Main outcome variables

mean and standard deviation of serum levels and gene expression of interleukins 4, 6, 10 and 17; TGF- β and IFN- γ in maternal and umbilical cord blood

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180304038943N1**
Registration date: **2018-04-17, 1397/01/28**
Registration timing: **prospective**

Last update: **2018-11-05, 1397/08/14**

Update count: **1**

Registration date

2018-04-17, 1397/01/28

Registrant information

Name

maryam Hadavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 8397

Email address

hadavi1344@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-17, 1396/12/26

Expected recruitment end date

2018-04-09, 1397/01/20

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2018-06-22, 1397/04/01

Trial completion date

2018-06-23, 1397/04/02

Scientific title

Comparison of the effect of general and spinal anesthesia on serum level and gene expression of interleukin 4, 6, 10 and 17; TGF- β and IFN- γ in maternal and umbelical cord blood in elective cesarean section

Public title

The anesthesia effect on serum levels and gene expression of interleukins in elective cesarean section

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Having reading and writing skills being at the age of 20 to 45 years single pregnancy term pregnancy without complications such as Corioamnionitis and preterm rupture of membrane

Exclusion criteria:

Unwanted pregnancy History of underlying illness including hypertension, diabetes, cardiovascular disease History of immunodeficiency diseases including HIV and hepatitis B mental disorders Inflammatory diseases History of drug abuse, smoking, Opium addiction

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to General or spinal anesthesia groups using sealed envelopes (40 sealed envelopes, 20 of which were marked with G = general anesthesia and 20 with the sign S = spinal anesthesia).

Blinding (investigator's opinion)

Single blinded

Blinding description

The person who will perform tests to measure interleukins, extract RNA and synthesize cDNA will be kept blind to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Molecular Medicine Research Center, Medical School, Khalije Fars Blvd., Pesteh Blvd.

City

Rafsanjan

Province

Kerman

Postal code

7716913411

Approval date

2017-01-09, 1395/10/20

Ethics committee reference number

IR.RUMS.REC.1395.125

Health conditions studied**1****Description of health condition studied**

The effect of anesthesia technique on the immune system

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

serum level of interleukin 4 in maternal blood before and after intervention

Timepoint

Measurement of serum level of IL-4 before study, after uterine incision, 2 hours after surgery, 24 hours after surgery

Method of measurement

ELISA test, Real Time PCR method

2**Description**

serum level of interleukin 6 in maternal blood before and after intervention

Timepoint

Measurement of serum level of IL-6 before study, after uterine incision, 2 hours after surgery, 24 hours after surgery

Method of measurement

ELISA test, Real Time PCR method

3

Description

serum level of interleukin 10 in maternal blood before and after intervention

Timepoint

Measurement of serum level of IL-10 before study, after uterine incision, 2 hours after surgery, 24 hours after surgery

Method of measurement

ELISA test, Real Time PCR method

4

Description

serum level of interleukin 17 in maternal blood before and after intervention

Timepoint

Measurement of serum level of IL-17 before study, after uterine incision, 2 hours after surgery, 24 hours after surgery

Method of measurement

ELISA test, Real Time PCR method

5

Description

serum level of interleukin IFN- γ in maternal blood before and after intervention

Timepoint

Measurement of serum level of IFN- γ before study, after uterine incision, 2 hours after surgery, 24 hours after surgery

Method of measurement

ELISA test, Real Time PCR method

6

Description

serum level of interleukin TGF- β in maternal blood before and after intervention

Timepoint

Measurement of serum level of TGF- β before study, after uterine incision, 2 hours after surgery, 24 hours after surgery

Method of measurement

ELISA test, Real Time PCR method

7

Description

Serum level of interleukin 4 in the umbilical cord blood of the baby

Timepoint

Immediately after birth

Method of measurement

Elisa test, Real Time PCR method

8

Description

Serum level of interleukin 6 in the umbilical cord blood of the baby

Timepoint

Immediately after birth

Method of measurement

ELISA test, Real Time PCR method

9

Description

Serum level of interleukin 10 in the umbilical cord blood of the baby

Timepoint

Immediately after birth

Method of measurement

ELISA test, Real Time PCR method

10

Description

Serum level of interleukin 17 in the umbilical cord blood of the baby

Timepoint

Immediately after birth

Method of measurement

ELISA test, Real Time PCR method

11

Description

Serum level of IFN- γ in the umbilical cord blood of the baby

Timepoint

Immediately after birth

Method of measurement

ELISA test, Real Time PCR method

12

Description

Serum level of TGF- β in the umbilical cord blood of the baby

Timepoint

Immediately after birth

Method of measurement

ELISA test, Real Time PCR method

Secondary outcomes

1

Description

post operative pain

Timepoint

6, 12 and 24 hours after surgery

Method of measurement

Visual Analog Scale (VAS)

Intervention groups

1

Description

Intervention group 1 (general anesthesia group): In this group, after controlling the vital signs and administration

of 100% oxygen using a mask and a pulse oximeter, induction of general anesthesia will be performed using thiopental, 4-6 mg / kg sodium and succinylcholine, 1-1.5 mg /kg. After tracheal intubation with Tube No. 7, oxygen and nitrous oxide are administered (50%). During the surgery Muscle relaxation will be performed using atracurium, 0.2-0.3 mg / kg.

Category

N/A

2

Description

Intervention group 2 (spinal anesthesia group): After controlling the vital signs, connecting the pulse oximeter's probe and starting the infusion of fluid, spinal anesthesia will be performed through injection of 0.5 ml marcaine (0.5% produced by AstraZeneca, Sweden) in the sub-arachnoid space using a quincke needle (produced in Japan), at the L3-L4 level in the sitting position. After administering the drug to the subarachnoid space, the patient will be placed immediately in the supine position.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Niknafs hospital

Full name of responsible person

Maryam Hadavi

Street address

Shohada Street

City

Rafsanjan

Province

Kerman

Postal code

7716913411

Phone

+98 34 3425 8397

Email

hadavi1344@ruma.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsyzadeh

Street address

Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7716913411

Phone

+98 34 3425 8397

Email

hadavi1344@rums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

maryam hadavi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Imam Ali Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7716913411

Phone

+98 34280038

Email

hadavi1344@rums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

maryam hadavi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Imam Ali Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7716913411

Phone

+98 34 3425 8397

Email

hadavi1344@rums.ac.ir

Phone

+98 34 3425 0038

Email

hadavi1344@rums.ac.ir

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

Yes - There is 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

Title and more details about the data/document

The gene expression, mean distribution and the standard deviation of interleukin in the two groups will share. Data will share without the attendee names.

When the data will become available and for how long

One year after publishing the results

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Research centers

From where data/document is obtainable

hadavimaryam@yahoo.com

What processes are involved for a request to access data/document

Sending an email to the responsible author, after the qualification of the applicant for a maximum of two months

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

Rafsanjan University of Medical Sciences

Full name of responsible person

maryam hadavi

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Rafsanjan University of Medical Sciences, Imam Ali Boulevard

City

Rafsanjan

Province

Kerman

Postal code

7716913411