Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 umbelical 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 performd 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)

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+98 34 3425 8397

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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 scienece
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 performd 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsyzadeh
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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

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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Position
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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