Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Relationship between serum and salivary biomarkers of oxidative stress during delivery and neonatal outcome in Fatemieh

Protocol summary

Summary

This clinical trial was performed in 2015 on 66 pregnant women hospitalized in Fatemieh hospital of hamedan, Iran. This study was performed aimed to assess the Relationship between serum and salivary biomarkers of oxidative stress during delivery and neonatal outcome. Inclusion criteria is The absence of acute and chronic complications of pregnancy and labor, singleton pregnancy full term pregnancy, lack of indications for cesarean and Exclusion criteria is the unwillingness of parents to continue to participate in the study. The patients were divided into two groups of Painless delivery and delivery with natural pain. When the cervix dilated 4-5 cm , in intervention group, a bolus of 17 mg of 0.125% bupivacaine injected in spinal space plus 10 microgram sufentanil (2cc) with 2 mg of bupivacaine injected epidural space. Before delivery, 5 ml of mother blood and 5 ml of mother saliva will be taken and after delivery ,5 ml of placenta blood will be taken too. The samples will be sent to the laboratory and then The index of total antioxidant, catalase enzymes and thiol groups will be measured. .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502266888N7**
Registration date: **2015-05-16, 1394/02/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan Universiy of Medical Sciences

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Iran (Islamic Republic of)

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+98 81 1827 6051

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shobeiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2015-02-04, 1393/11/15

Expected recruitment end date

2015-06-05, 1394/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Relationship between serum and salivary biomarkers of oxidative stress during delivery and neonatal outcome in Fatemieh

Public title

The levels of oxidative stress biomarkers during labor

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria: The absence of acute and chronic complications of pregnancy and labor, singleton pregnancy full term pregnancy, lack of indications for cesarean Exclusion criteria: the unwillingness of parents to continue to participate in the study.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

65178

Approval date

2015-01-12, 1393/10/22

Ethics committee reference number

5148/1/35/16/پ

Health conditions studied

1

Description of health condition studied

Biomarkers of oxidative stress during labor

ICD-10 code

P00-P96

ICD-10 code description

Certain conditions originating in the perinatal period

Primary outcomes

1

Description

total Antioxidant capacity

Timepoint

After the intervention at 8-9 cm dilatation

Method of measurement

In umol / ml by using FRAP

2

Description

Catalase enzyme

Timepoint

After the intervention at 8-9 cm dilatation

Method of measurement

In umol / ml by using TBA

3

Description

Thiol groups

Timepoint

After the intervention at 8-9 cm dilatation

Method of measurement

In MMol by using laboratory techniques

Secondary outcomes

1

Description

Hypotension

Timepoint

Continuous monitoring of blood pressure after the intervention up to 2 hours after delivery

Method of measurement

pressure on the Mm Hg using a sphygmomanometer

2

Description

hyperthermia

Timepoint

Continuous monitoring of body temperature after intervention Up to 2 hours postpartum

Method of measurement

body temperature in Mm Hg using an oral thermometer

3

Description

Increasing duration of delivery

Timepoint

Every two hours after the intervention

Method of measurement

Partograghy form

Intervention groups

1

Description

Control group: Usual care or no intervention will receive

Category

Diagnosis

2

Description
Group Intervention: The intervention consisted of a combination of local anesthesia administered during the active phase of labor and 3-4 cm cervical dilatation. we used of Marcaine with a concentration of ./125 The rate of 17 mg for spinal anesthesia and the solution sufentanil 1/7 cc & Marcaine with 2 mg used for spinal anesthesia
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital of Hamadan
Full name of responsible person
Fatemeh Shobeiri
Street address
Kermanshah Street, Pasdaran Avenue, Hamadan, Iran
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan university of medical sciences
Full name of responsible person
Heidar Tavilani
Street address
No. 307, Fahmideh Street, Hamadan University of Medical sciences Hamadan
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Hamadan University of Medical sciences
Full name of responsible person
Fatemeh Shobeiri
Position
Ph.D. in Maternal and Child Health
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty