Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison between analgesic effect of intra dermal and sub dermal injection of sterile water on active labor pain

Protocol summary

Study aim

Comparison between the analgesic effect of subdermal and intradermal injection of sterile water on labor pain

Design

randomized Clinical trial with 2 intervention and 1 placebo group parallel and double blind

Settings and conduct

The samples are pregnant, nulliparous, ≥37 weeks gestation women, 15-40 years old that will come to labor room of Akbarabadi Hospital. The women that have ≥4 cm dilatation and will sign the inform consent will enter the research. In first group gynecologic resident will inject 0.1 cc sterile water on sacral region intradermally (on posterior superior iliac spine of each side) and another 0.1 cc two cm upper and outer. In second group the same amount of sterile water will be injected on the same sites and in third group we will only contact the needle with the same sites of sacral skin. The sample size in each group is 40. The gynecologic resident will do the injections in LDR and only she will know the rout of injection. The midwife of labor room will do the VAS test before intervention and 10, 30, 40, 90 and 120 minutes after intervention. The data will be analyzed by SPSS 22 by using T test and chi- square test and for finding the correlation pearson,correlation coefficient.

Participants/Inclusion and exclusion criteria

include criteria: 1- Nulliparity 2-dilatation 4 cm or more 3. Cephalic 4- 37 weeks or more exclude criteria: 1. not filled inform consent 2. multi parity 3. history of lower abdominal or back pain before pregnancy 4. fetal demise 5. lesion or infection of injection site 6. coagulation disorders

Intervention groups

In first group 0.5 cc sterile water will be injected intradermal and in second group, subdermal. In third group we will have only contact of needle with skin

Main outcome variables

Comparison of severity of labor pain in 3 groups

General information

Reason for update

Acronym

The effect of sterile water injection on active labor pain

IRCT registration information

IRCT registration number: **IRCT20170924036365N2**
Registration date: **2019-03-18, 1397/12/27**
Registration timing: **retrospective**

Last update: **2019-03-18, 1397/12/27**
Update count: **0**

Registration date

2019-03-18, 1397/12/27

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9283

Email address

almassi@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-16, 1397/09/25

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

2018-07-10, 1397/04/19

Actual recruitment end date

2018-11-09, 1397/08/18

Trial completion date

2018-11-09, 1397/08/18

Scientific title

Comparison between analgesic effect of intra dermal and sub dermal injection of sterile water on active labor pain

Public title
effect of intra dermal and sub dermal injection of sterile water on active labor pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
first pregnancy(nulliparyte) dilatation of cervix 4cm or more cephalic baby gestational age 37w or more and planned for vaginal delivery
Exclusion criteria:
No inform consent Multi parity History of low back pain or abdominal pain unrelated to delivery fetal demise Skin lesion or infection on injection site coagulation disorders of mother
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
1-Randomization will be done by using random allocation table. The gynecologic resident will do all of the injections
Blinding (investigator's opinion)
Double blinded
Blinding description
The midwife of labor will do all of the VAS tests. The gynecologic resident of this research will do all of the injections in LDR. The midwife of labor dose not know that witch method is done for each mother.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University medical sciences ethic committee, Hemmat high way, Tehran , Iran
City
Tehran
Province
Tehran
Postal code
1467664961
Approval date
2017-05-21, 1396/02/31
Ethics committee reference number
IR.IUMS.FMD.REC.1397.012

Health conditions studied

1

Description of health condition studied
labor pain
ICD-10 code
047.1
ICD-10 code description
047.1

Primary outcomes

1

Description
Severity of pain
Timepoint
before intervention and 10,30,60,90, and 120 minute after intervention
Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group- To 40 patient, 0.5 cc sterile water will be injected subdermal with the insulin needle in the four sacral area (two injections in the posterior superior iliac spine and two other injections of one centimeter outer and two centimeters upper than the first place)
Category
Treatment - Other

2

Description
Second intervention group- in 40 women, 0.5 cc sterile water will be injected intradermal with the insulin needle in the four sacral area (two injections in the posterior superior iliac spine and two other injections of two centimeter outer and two centimeters upper than the

first place)

Category

Treatment - Other

3

Description

Control group- Just touch the tip of the needle with the skin of sacral area

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi hospital

Full name of responsible person

Fariba Almassi

Street address

Iran University of medical sciences, Hemmat high way, Tehran

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Sponsors / Funding sources

1

Sponsor

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Fariba Almassi

Position

Professor in obstetrics and gynecology

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Nassim Ahani
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Resident of gynecology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
By publishing article resulted from this research
When the data will become available and for how long
One year later
To whom data/document is available
All of the people that read the article
Under which criteria data/document could be used
Only Dr Fariba Almassi
From where data/document is obtainable
1-By reading the article 2-By contact with Dr Fariba Almassi
What processes are involved for a request to access data/document
Until 1 year after publication, during 6 months after contact the data will be emailed
Comments