Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Survey of Back Pain Reduction With and Without Subcutaneous Sterile Water Injection In Women With Active Phase of Labor

Protocol summary

Study aim

Determination of the effect of subcutaneous sterile water injection on reducing back pain of women in active phase of labor

Design

This is a randomized single blind clinical trial. We will have three groups, intervention, control and sham groups. First, the order of these three groups is determined by lottery. From the day of the start of the sampling, the women who will refer to the hospital on the first day will be in the first group. Women in the second day will be in the second group and women on the third day will be in the third group.

Settings and conduct

This study was performed on 90 patients in Afzalipour Kerman hospital in three groups of 30 patients. Intervention group (Injection of 0.5 ml sterile water subcutaneously in 4 site of sacrum), Control group (insertion of needle Without injection of certain material in 4 site of sacrum), Sham group (without needle and injection). The study is done single blind. Women will not be aware of the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-35 years, Term pregnancy (38-42 weeks), Singleton live fetus with an approximate weight of more than 2500 grams Exclusion criteria: No informed consist, Any systemic illness

Intervention groups

The intervention group: Injection of 0.5 ml of sterile distilled water subcutaneously into 4 site of sacrum Control group : Insertion of needles without injection of specific material in 4 site of sacrum Sham group: without needle insertion and injection

Main outcome variables

The main outcome of this study is the amount of women's lumbar pain that is expected to be reduced by distilled water. injection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181023041427N1**
Registration date: **2018-12-19, 1397/09/28**
Registration timing: **retrospective**

Last update: **2018-12-19, 1397/09/28**
Update count: **0**

Registration date

2018-12-19, 1397/09/28

Registrant information

Name

Farzaneh Khajehnazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4220 8281

Email address

f.khajehnazari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-08-22, 1397/05/31

Trial completion date

2018-09-22, 1397/06/31

Scientific title

Survey of Back Pain Reduction With and Without Subcutaneous Sterile Water Injection In Women With Active Phase of Labor

Public title
Effect of subcutaneous sterile water injection on back pain of Women with Active Phase of Labor
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Nulliparous women with an Iranian nationality Women 18-35 years old Term pregnancy (38-42 weeks) Start of uterine contractions and active phase of labor pain in the lower back Śingleton live fetus with a weight of over 2500 grams The embryo with anterior occiputa position the absence of sedative drugs, systemic and topical analgesic drugs use up to ninety minutes after intervention
Exclusion criteria:
No Informed consent Any systemic disease associated with pregnancy including diabetes, hypertension, heart diseases, etc., History of narcotic and alcohol consumption, history of psychiatric illness and depression Trauma created during childbirth (when using labor tools such as forceps or vacuum, a large perineal rupture, postpartum hemorrhage, etc.) Any need for emergency intervention for maternal and fetal reasons such as placenta abruption Maternal hospitalization during pregnancy Emergency cesarean delivery for any reason during labor
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization Randomization unit: individual
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, participants will blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Haft bagh Alavi BLVD, Principal of Kerman University of Medical Sciences
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2018-02-03, 1396/11/14
Ethics committee reference number
IR.KMU.REC.1396.2183

Health conditions studied

1

Description of health condition studied
Active labor phase
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Labor pain
Timepoint
10, 45 and 90 Minutes after injection
Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of 0.5 ml sterile water subcutaneously in 4 site of sacrum
Category
Treatment - Drugs

2

Description
Control group : Insertion of needle without injection of certain material in 4 site of sacrum
Category

Placebo

3

Description
Sham group: Without injection
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour Hospital
Full name of responsible person
Farzaneh khajehnazari
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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Web page address
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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
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Farzane khajehnazari
Position
Obstetrics-Gynecology resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Position

Obstetrics-Gynecology resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

Data will be shared after coding.

When the data will become available and for how long

Access period 6 months after the publishing of results

To whom data/document is available

Researchers working in Universities

Under which criteria data/document could be used

Any redistribution or use of the information is permitted by reference to the source.

From where data/document is obtainable

Farzaneh khajeh nazari, f.khajehnazari@gmail.com

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

By email and by Presenting valid identification card

Comments