

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Will Subcutaneous Injection of Distilled Water Lessen the Back Pain in Active Phase of Labour

Protocol summary

Summary

Labor pain is one of the worst pains women experience during their life and its one of the reasons of increase in Caesarean section incidents. Many ways to reduce this pain is invented, one of which is the injection of distilled water in sacrum area subcutaneously. The aim of this study is to evaluate the effect of this therapeutic method. This study is a double blinded clinical trial. 160 primigravid women were recruited into two groups, cases and controls. In cases group distilled water was injected subcutaneously in sacrum area while normal saline was used in controls group and the pain degree was measured using VAS method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202253547N2**

Registration date: **2012-03-04, 1390/12/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-04, 1390/12/14

Registrant information

Name

Mohammad Nadjafi-Semnani

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 9551

Email address

nadjafi@hbi.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical sciences

Expected recruitment start date

2006-12-22, 1385/10/01

Expected recruitment end date

2009-08-23, 1388/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Will Subcutaneous Injection of Distilled Water Lessen the Back Pain in Active Phase of Labour

Public title

Will Subcutaneous Injection of Distilled Water Reduce the Back Pain in Active Phase of Labour

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: term pregnancy, alive fetus and active phase of labour. Exclusion criteria: preterm labour; fetal death; labour induction (oxytocin prostaglandin) and use of sedatives

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Etich committee of Birjand university of medical sciences
Street address
Moalem St.
City
Birjand
Postal code
9713667649
Approval date
2006-12-09, 1385/09/18
Ethics committee reference number
143

Health conditions studied

1

Description of health condition studied
Normal delivery
ICD-10 code
Z34
ICD-10 code description
Supervision of normal pregnancy

Primary outcomes

1

Description
Pain
Timepoint
At the begging of the study and minutes: 40, 60 and 90.
Method of measurement
Visual analogue scale

Secondary outcomes

1

Description

Demand for sedative
Timepoint
At the end of the study
Method of measurement
Questionnaire

2

Description
Patient satisfaction from treatment
Timepoint
At the end of the study
Method of measurement
Questionnaire

Intervention groups

1

Description
In controls group, normal saline was injected subcutaneously in sacrum area
Category
Placebo

2

Description
In cases group distilled water was injected subcutaneously in sacrum area.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Nahid Ghanbarzadeh
Street address
Birjand Valiasr hospital
City
Brjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Shairfzadeh
Street address
Ghafary street
City
Birjand
Grant name
Grant code / Reference number

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

Yes

Title of funding source

Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Nahid Ghanbarzadeh

Position

Gynecologist-

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences

City

Birjand

Postal code**Phone**

+98 56 1222 9129

Fax**Email**

nghanbarzadeh@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Nahid Ghanbarzadeh

Position

Gynecologist

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences

City

Birjand

Postal code**Phone**

+98 56 1222 9129

Fax**Email**

nghanbarzadeh@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Mohammad Najafi Semnani

Position

Associate professor

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences

City

Birjand

Postal code**Phone**

+98 56 1222 8499

Fax**Email**

monadjafi@gmail.com

Web page address**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