

# 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

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+98 56 1222 9129

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Birjand University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Najafi Semnani

**Position**

Associate professor

**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*