

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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,  $\geq 37$  weeks gestation women, 15-40 years old that will come to labor room of Akbarabadi Hospital. The women that have  $\geq 4$  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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1168743514

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Fariba Almassinokiani

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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**

**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 updating data

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Nassim Ahani

**Position**

Resident of gynecology

**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**

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**