Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparative study of the effect of subcutaneous and intracutaneous injection of distilled sterilized water and normal saline on the severity of pain, duration, and some outcomes of labor in primipara women

Protocol summary

Study aim

Determine the effect of intracutaneous and subcutaneous injection of distilled sterilized water on the severity of pain and the duration of the active phase of the first stage of labor in primipara women

Design

The clinical trial included two intervention groups and two control groups، with parallel groups,triple blind, randomized trials, randomized using cards with numbers from 1 to 4, design of 164 sample, sampling from 05/05/2013 to 23/09/2014

Settings and conduct

Based on the inclusion criteria and obtaining a written consent of the samples about how to do the study, information about pain intensity at 5 minutes before injection and 30, 60, 90, 120, 150, 180 minutes after injection, duration of the active phase of the first stage of labor, duration of the second stage of labor, delivery type, delivery satisfaction, perineum status, type and degree of rupture through the examination and interviews were collected. The severity of pain was measured by McGill's visual analogue scale pain. In order to randomize, the cards are prepared and four numbers 1, 2, 3, and 4 are written and placed inside the packets in an unspecified manner and research unit remove one of the envelopes, if there is a number 1 in the group of intracutaneous of injection distilled sterilized water, number 2 subcutaneous injection of distilled sterilized water, number 3 in the group intracutaneous of injection normal saline and number 4 in the subcutaneous group of injection normal saline are placed.In groups 1 and 3, at each point Michael 's rhomboid 0.15 cc and in groups 2 and 4, at each point a 0.5 ml distilled sterilized water or normal saline was injected. Injection is performed in each of the four groups at intervals between contractions in the sitting position by insulin syringe. In order to blind the study the assessor from the group assigned to the samples is not aware.The researcher does not know from the group assigned to the specimens.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged between 18 and 35 years old, prmiparous women, Gestational age between full 37-41 weeks, singleton pregnancy; non-compliance criterion: All high risk pregnant women (preeclampsia, diabetes, oligo-hydramonious, polyhydramnious, etc.), using any pharmacological or non-pharmacological method to reduce pain in the course of labor

Intervention groups

Intracutaneous injection of distilled sterilized water, subcutaneous injection of distilled sterilized water, intracutaneous injection of normal saline, subcutaneous injection of normal saline

Main outcome variables

The main consequences include the severity of labor pain; duration of the active phase of the first stage of labor; duration of the second stage of labor; type of delivery; satisfaction of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180128038535N1**
Registration date: **2018-02-22, 1396/12/03**
Registration timing: **retrospective**

Last update: **2018-02-22, 1396/12/03**
Update count: **0**

Registration date

2018-02-22, 1396/12/03

Registrant information

Name

Mehri Rezaie

Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 86 4223 0789
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2013-05-05, 1392/02/15
Expected recruitment end date
2014-05-05, 1393/02/15
Actual recruitment start date
2013-05-05, 1392/02/15
Actual recruitment end date
2014-09-23, 1393/07/01
Trial completion date
empty

Scientific title
Comparative study of the effect of subcutaneous and intracutaneous injection of distilled sterilized water and normal saline on the severity of pain, duration, and some outcomes of labor in primipara women

Public title
The effect of subcutaneous and intracutaneous injection of distilled sterilized water and normal saline on the severity of childbirth pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged between 18 and 35 years old Primiparous women Gestational age between 37-41 full weeks Singletone pregnancy Head presentation There are at least 3 contractions in 10 minutes Dilatation of cervix 4-6 cm Fetus station -1 to down Effacement of cervix more than 50%
Exclusion criteria:
All high risk pregnant women (preeclampsia, diabetes, oligo-hydramnios, polyhydramnios, etc) Applying any pharmacological or non-pharmacological method to reduce labor pain Drug abuse Fetal distress
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **164**
Actual sample size reached: **164**

Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize, the cards are prepared and four numbers 1, 2, 3, and 4 are written and placed inside the packets in an unspecified manner and research unit remove one of the envelopes, if there is a number 1 in the group of intracutaneous of injection distilled sterilized water, number 2 subcutaneous injection of distilled sterilized water, number 3 in the group intracutaneous of injection normal saline and number 4 in the subcutaneous group of injection normal saline are placed.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Clinical care (interventionist) is unaware of the goals of the study.The assessor from the group assigned to the samples is not aware.The researcher does not know from the group assigned to the specimens.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Jahrom University of Medical Sciences
Street address
Ostad Motahari Bvld, University campus
City
Jahrom
Province
Fars
Postal code
7414846199
Approval date
2013-02-01, 1391/11/13
Ethics committee reference number
IR.JUMS.REC.139.076

Health conditions studied

1

Description of health condition studied
Study of the effect of injection distilled sterilized water and normal saline on the severity of labor pain
ICD-10 code
R52.9
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Severity of labor pain
Timepoint
5 minutes before the intervention and 30, 60, 90, 120, 150 and 180 minutes after the intervention
Method of measurement
Visual analogue Scale of McGill Pain

2

Description
Duration of the active phase of the first stage of labor
Timepoint
Immediately after intervention
Method of measurement
Kronometer

3

Description
Duration of the second stage of laborپس از مداخله
Timepoint
After the intervention
Method of measurement
Kronometer

4

Description
Satisfaction of delivery
Timepoint
After the intervention
Method of measurement
questionnaire

5

Description
Type of delivery
Timepoint
After the intervention
Method of measurement
observation

Secondary outcomes

1

Description
Perineum status after delivery
Timepoint
after the intervention
Method of measurement
Observation and examination

2

Description
Tear type
Timepoint
after the intervention
Method of measurement
Observation and examination

3

Description
Rupture degree
Timepoint
after the intervention
Method of measurement
Observation and examination

Intervention groups

1

Description
Intervention group:Intracutaneous injection of distilled sterilized water
Category
Treatment - Other

2

Description
Intervention group: Subcutaneous injection of distilled sterilized water
Category
Treatment - Other

3

Description
control group: Intracutaneous normal saline injection
Category
Treatment - Other

4

Description
Control group: Subcateneous normal saline injection
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ostad Motahari hospital of Jahrom
Full name of responsible person
Mehri Rezaie
Street address
Ostad Motahari Blvd
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5415713597

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Jahrom University of Medical Sciences

Full name of responsible person
Kavoos Solhjou

Street address
University campus, Ostad Motahari Bvld

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7414846199

Phone
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Email
solhjouk@yahoo.com

Grant name
HSR

Grant code / Reference number
94

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

Title of funding source
Jahrom 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
Jahrom University of Medical Sciences

Full name of responsible person
Mehri Rezaie

Position
Non-faculty midwife

Latest degree
Master

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available