Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of Swedish massage and Interferential Electrical Stimulation on labor pain and childbirth experience in primipara women: a randomized controlled clinical trial

Protocol summary

Study aim

The aim of this study is compare the effect of Swedish massage and Interferential Electrical Stimulation on labor pain and childbirth experience in primipara women.

Design

This study is a randomized controlled clinical trial on 90 primiparous women. participants randomly will allocated based on 6 and 9 blocks randomization with stratification for perceived induction or lack of induction by ratio of 1: 1: 1 into 3 groups(Swedish massage, Interferential Electrical Stimulation and control).kind of intervention will be done with sequentially numbered, opaque, sealed envelopes by a person not involved in the study

Settings and conduct

This single blind study at Alzahra& talegani Hospital will be a blinded outcome asessor and analyze

Participants/Inclusion and exclusion criteria

Primiparous, Singleton, gestational age 38-40 weeks, beginning of active phase,intact sac, low risk pregnancy Chronic systemic disease, meconium-stained amniotic fluid,skin problem and bone fracture, delivery analgesia.

Intervention groups

In the Interfrancial group, 30 to 45 minutes of electrical stimulation in 4 cm dilatation of cervix will be applied on T10 -L1 in 5 cm of the para-spinal area and 30 to 45 minutes in 8 to 10 cm of cervix dilatation onS2-S4 with a base frequency of 4000 Hz and a pulse frequency of 80 to 120 Hz and Pulse duration of 50 to 60 microseconds. In Swedish massage group, Effleurage and petrissage massages will be used at the same sites and same times.Effleurage technique, which including superficial motions crisscross, circular, knuckle and thousand hand and Petriages including rolling and kneading.The control group will receive only routine care.

Main outcome variables

Pain will be measured in all groups before the intervention, every hour to the second stage of labor and one hour after delivery by using VAS. The labor experience of 12-24 hours after delivery will measured by using LAS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110524006582N32**
Registration date: **2019-12-07, 1398/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**
Update count: **0**

Registration date

2019-12-07, 1398/09/16

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of Swedish massage and Interferential Electrical Stimulation on labor pain and childbirth experience in primipara women: a randomized controlled clinical trial

Public title
Comparison the effect of Swedish massage and Interferential Electrical Stimulation on labor pain and childbirth experience in primipara women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being nulliparous Being Singleton Gestational age 38 to 40 weeks Being at the beginning of the active phase (dilatation 4 cm) cephalic presentation of fetus, Having a intact membranes, No Drug Addiction and Smoking, existence of low-risk pregnancy without medical complications in pregnancy, including hypertension, gestational diabetes, twins and multiple pregnancy , placenta and amniotic fluid disorders and ....
Exclusion criteria:
A history of chronic systemic, cardiac, pulmonary diseases according to the patient himself meconium-stained amniotic fluid before intervention Any skin problem in the areas of electrodes, existence any skin disorders and fractures in the site of massage Allergy to olive oil People receiving Painless delivery of medication (receiving epidural anesthetics and intravenous infusion of remifentanil) People receiving other non-pharmacological analgesics
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **30**
30 persons in each group
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be Convenience sampling or availability sampling. For this purpose, all women admitted to the Alzahra hospital and taleghani hospital in the delivery ward will be examined for entry and exit criteria, and if they are eligible and have a willingness to participate in the study, they will fully explain their goals and method of study. Participants by block randomization with stratification for perceived induction or lack of induction and with blocks size of 6× 9 will allocated by the allocation ratio of 1: 1: 1 into three groups (Group 1: Receiving of Swedish massage group Second: Receiving of Interferential Electrical Stimulation and the third group: control group). To Allocation Concealement, the type of intervention will be written on a sheet of paper and placed inside the sequentially numbered, opaque, sealed envelopes. Envelopes will be displayed in the order of participation of the participants in the study and the type of intervention received will be determined.The research assistant who is not familiar with how to allocate groups will be used to complete the delivery experience questionnaire to prevent bias.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the outcome assessor and the data analyzer will be blind of the group allocation.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences Research Administration
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2019-10-24, 1398/08/02
Ethics committee reference number
IR.TBZMED.REC.1398.751

Health conditions studied

1

Description of health condition studied
pain and experince of child birth
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
-Comparison of the mean score of labor pain among the study groups
Timepoint
Pain score in all three groups before intervention, then every hour until the second stage of labor and one hour after delivery
Method of measurement
Using the VAS scale(Visual Analogue Scale)

2

Description
Comparison of mean score of labor experience among study groups
Timepoint
12-24 hours after childbirth
Method of measurement
Using LAS (Labor Agentry Scale)

Secondary outcomes

1

Description
Comparison of duration of active phase of labor among study groups
Timepoint
From the dilatation of 4 cm until the baby's exit, following the examinations performed by the researcher, the partograph graph will be filled and is drawn.
Method of measurement
Using the Partograph

2

Description
Comparison of the mean of satisfaction score of delivery among the study groups
Timepoint
12-24 hours after childbirth
Method of measurement
Using the Mackey Scale

3

Description
Comparison of fetal heart rate disorders among study groups
Timepoint
Each hour will be controlled by the researcher.
Method of measurement
It will be recorded in the checklist.

4

Description
Comparison of the Apgar score of the first and fifth minutes among the study groups
Timepoint
In the first and fifth minutes after childbirth
Method of measurement
It will be recorded in the checklist.

Intervention groups

1

Description
Intervention group: People who will receive the Swedish massage.
Category
Treatment - Other

2

Description
Intervention group: People who will receive the Interferential Electrical Stimulation
Category
Treatment - Other

3

Description
Control group: People who only will receive routine care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital in Tabriz
Full name of responsible person
Mahsa Maghailan
Street address
Tabriz khademe glorok street, Alley of shahid samadi No. 6
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for reaserch, University Of Tabriz Medical Sciences
Full name of responsible person
mohammad Samiei
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Golgasht Street, Research Office, No 2 Central Building, Tabriz University of Medical Sciences,
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5138947977
Phone
+98 41 3479 6770
Email
samiei.moh@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
vice chancellor for reaserch, University Of Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mahin Kamalifard
Position
هیئت علمی
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information.
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