# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 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**
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بیمارستان طالقانی تبریز
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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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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**
Master
**Other areas of specialty/work**
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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