Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Solvia oil in two methods of Massage and Aromatherapy on intensity of labor pain in primiparous women

Protocol summary

Study aim

Determination of the Effect of solvia Oil by Massage and Aromatherapy on intensity of labor Pain in Primiparous Women

Design

28 people in each group were evaluated and 10% drop, the sample size was 32 in each group and 96 in each group. Also, the division of samples into groups is completely randomized using 6 blocks.

Settings and conduct

The population under study is all primiparous women who come to the Besat Hospital in Sanandaj for delivery at the time of sampling and have criteria for entering the study.

Participants/Inclusion and exclusion criteria

The study population is all primiparous women who come to the Besat Hospital in Sanandaj for the purpose of delivery at the time of sampling and have criteria for entering the study women aged 18-40, gestational age between 37-37 weeks, dilation 4-3 Centimeters, at least literate reading and writing, represent the head of the fetus.

Intervention groups

The group in this study is generally the intervention group (A, B) and control (C): 1. Group A: Group A (Aromatherapy with solvia oil) In this group, women smell the herbal syringe with 10% bean oil for 20 minutes. The pain intensity is recorded after 20 minutes. 2.Group B (Massage Therapy with solvia oil) In this group, women receive 20% of the back massage by using an apple juice extract of 10% for 20 minutes, and the intensity of pain is recorded after 20 minutes. 3. Group C (control) In this group, women will receive routine care and no intervention will be given to them. 20 minutes later, the severity of the pain is felt and recorded.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190322043098N1**
Registration date: **2019-04-27, 1398/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**
Update count: **0**

Registration date

2019-04-27, 1398/02/07

Registrant information

Name

Bahare Noori monfared

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 4612 9104

Email address

norimonfared.b@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Solvia oil in two methods of Massage and Aromatherapy on intensity of labor pain in primiparous women

Public title
Comparison of the effect of Solvia oil in two methods of Massage and Aromatherapy on intensity of labor pain in primiparous women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
The desire to participate in the study Women aged 40-18 Pregnancy age between 42-37 weeks 4-3 cm dilatation At least reading and writing skills Having a natural garden before studying Not having a midwife along Exposure to the embryo Not having diseases like cancer, lumbar disc disease, high blood pressure, seizures, diabetes, high fever, infectious disease,
Exclusion criteria:
Rupture more than 6 hours a bottle of water Get anorexia three hours before the study begins Multiplayer women Known mental illness Surgery of the spine in the last three months The occurrence of any stressful event involving the separation of the spouse, the death of the loved ones within the past six months Drug Addiction and Psychosocial History of sensation and allergy to fragrances Third-trimester bleeding Abortion history
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
---Examples of each group for the statistical counselor will be unknown.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kurdistan University of Medical Sciences
Street address
Kurdistan University of Medical Sciences Pasdaran Blvd,
City
Sanandaj
Province
Kurdistan
Postal code
6617715175
Approval date
2019-03-19, 1397/12/28
Ethics committee reference number
IR.MUK.REC.1397.387

Health conditions studied

1

Description of health condition studied
-
ICD-10 code
ICD-10 code description
-

Primary outcomes

1

Description
The severity of labor pain is measured based on a pain reliever
Timepoint
-In dilates of 5-4, 7-6 and 8-10 cm cervix before and after intervention in the studied groups
Method of measurement
Based on the visual scale of the pain, which is a 10-cm ruler, the zero number on the left indicates no pain and the number 10 on the right

Secondary outcomes

empty

Intervention groups

1

Description
1. Group A: Group A (aromatherapy with solvia oil) In this study, women have a sensation of 5-4, 7-6, and 10-8 cm dilatations. The herbal scent is smeared with 10% bean oil for 20 minutes, and the severity of pain after 20 Minutes are recorded.
Category
Rehabilitation

2

Description
Group B: Group B (Massage Therapy with solvia oil) In

this study, women who have been treated with an extract of essential oil in a 4x4, 7-6, and 10-8cm dilates for 20 minutes, 10 percent made by Healing Kurdistan Corporation. And the severity of pain is recorded after 20 minutes.

Category
Rehabilitation

3

Description
Control group: In the study, the group C (control) in this study is women who have routine care in dilates 5-4, 7-6 and 10-8

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Hospital

Full name of responsible person
Bahareh Noori Monfared

Street address
Keshavarz Street, Meroux

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Sanandaj

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6618634683

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Nouri.b1365@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sanandaj University of Medical Sciences

Full name of responsible person
Farzin Rezaei

Street address
Kurdistan University of Medical Sciences, Pasdaran Boulevard

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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
Sanandaj 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
Sanandaj University of Medical Sciences

Full name of responsible person
Bahareh Noori Monfared

Position
Master Student Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Farzaneh Zaheri

Position
Master's assistant

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact
Name of organization / entity
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Bahareh Noori Monfared
Position
Master of Science in Midwifery
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Information on the effect of the herbal extracts on the severity of labor pain will be released.primiparous women admitted to the delivery ward of Beasat Hospital in Sanandaj in 2019.
When the data will become available and for how long
-Start the access period 6 months after printing the results
To whom data/document is available
-Researchers working in academic institutions and pharmaceutical companies
Under which criteria data/document could be used
-No institution and anyone else has access.
From where data/document is obtainable
bahareh noori monfared nouri.b1365@gmail.com 09189294236
What processes are involved for a request to access data/document
-After accessing the data and verifying the request by the researcher and the research executor, data is provided to individuals or institutions within at least three months.
Comments
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