

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the Effect of hydroalcoholic extract of Clove plants on the Severity of Pain and Episiotomy Wound Healing in Pregnant mothers

Protocol summary

Study aim

Determination of the effect of hydroalcoholic extract of clove plantlets on the severity of pain and Wound Healing in mothers

Design

The clinical trial has two groups of control and intermediate, two blind and randomized control group

Settings and conduct

146 pregnant women over 20 weeks of age and those who are pregnant are referred to the health centers. Using the random number table, the sample size is completed and then again using the random numbers of the individuals into two groups Intervention and control will be allocated. On the mothers' checklist, they will be written in the intervention and control groups A and B. Then, at the time of delivery and after the episiotomy, the sample is entered into the study. Which is given to the mothers in the intervention group of glass and the solution of cloves, and to the control group of glass containing distilled water, and the use of the solution for both groups will be explained. This study is also a blind one.

Participants/Inclusion and exclusion criteria

Age aged 18-35, Have at least read and write, Having a natural delivery plan, Negative relationship, no indication for cesarean section, Body mass index in range 19.8-29, Embryo unit with Vertex display, Not having a midwifery history, Maternal admission after the 20th week of pregnancy, Pregnancy longer than or equal to 37 weeks, No history of medical and mental illness, Lack of curettage, Rupture of curtains less 10 hours, No history of reconstructive surgery on the vagina and mandarin, No use of certain medications

Intervention groups

Mothers in the intervention group will receive 0.25 mg of clove solution and the mothers will be given the same amount of distilled water as the placebo and the mother will be asked to mix 0.25 mg of the solution twice in 10 days in 4 liters of water and sit for 30 minutes in it.

Main outcome variables

Episiotomy pain; Wound Healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181216041990N1**

Registration date: **2018-12-26, 1397/10/05**

Registration timing: **prospective**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

Registration date

2018-12-26, 1397/10/05

Registrant information

Name

Saeideh Rajabzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3273 1424

Email address

s.rajabzadeh@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-05-31, 1398/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of hydroalcoholic extract of Clove plants on the Severity of Pain and Episiotomy Wound Healing in Pregnant mothers

Public title

Investigating the Effect of hydroalcoholic extract of Clove plants on the Severity of Pain and Episiotomy Wound Healing in Pregnant mothers

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age aged 18-35 Have at least read and write Having a natural delivery plan Life with yours Not having an indication for cesarean section Body mass index in range 19.8-29 Embryo unit with Vertex display Having a midwifery history Maternal admission after the 20th week of pregnancy No history of medical and mental illness Rupture of curtains less 10 hours Lack of curettage No history of reconstructive surgery on the vagina and mandarin No use of certain medications

Exclusion criteria:**Age**

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Pregnant women are assigned to a randomized and assigned sample size and inclusion criteria are assigned to intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the participating mothers will not be informed about the type of the use of the solution. Also, the clinical care and research will not be informed about the type of solution.

Placebo

Used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Sentoo road border, Gonabad Town

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.GMU.REC.1397.090

Health conditions studied**1****Description of health condition studied**

the Severity of Pain and Episiotomy Wound Healing

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

the Severity of Pain and Episiotomy Wound Healing

Timepoint

Before intervention and On days 3 to 5 and 10 after intervention

Method of measurement

Visual Analogue Scale and REDA

Secondary outcomes**1****Description**

Pain rate

Timepoint

Before the intervention and every 3 to 5 and 10 days after the intervention

Method of measurement

Visual Analogue Scale

2**Description**

episiotomy Wound healing

Timepoint

Before the intervention and every 3 to 5 and 10 days

after the intervention
Method of measurement
READA

Intervention groups

1

Description

Intervention group: Take 0.25 ml of clove extract in 4 liters of water and leave twice for 30 minutes.

Category

Treatment - Other

2

Description

Control group: Place 0.25 ml of the placebo solution in 4 liters of water and sit twice for 30 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Ferdows Hospital

Full name of responsible person

Saeideh Rajabzadeh

Street address

Shahid chamran Hospital, Motehari street

City

Ferdows

Province

South Khorasan

Postal code

9691793718

Phone

+98 56 3272 2801

Email

s.rajabzadeh@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr.Sayed Ali Sajjadi

Street address

Gonabad University of Medical Sciences,the beginning of the Sento Road.Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 5027

Email

sajjadi@gmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Saeideh Rajabzadeh

Position

Students

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Saeideh Rajabzadeh

Position

Student

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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