

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of citrus aurantium essential oil on the severity of pain in the first and second stages of labor and childbirth Satisfaction with delivery in primegravida women

#### Protocol summary

##### Study aim

the effect of Spring orange essential oil on the severity of pain in the first and second stages and satisfaction of childbirth

##### Design

the researcher will start sampling available (easy) after obtaining the informed consent of the eligible women. The research units will then be assigned to two intervention and control groups using quadruple blocks.

##### Settings and conduct

In Allameh Behloul Gonabadi Hospital, the samples were randomly assigned to one of the two experimental or control groups. After obtaining informed consent at the beginning of the active delivery phase (3-4 cm dilatation) in the intervention group, 4 ml of spring orange essential oil is poured on the absorbable, odorless and one-size napkin and attached to the collar of their clothes with a pin. In the control group, instead of spring essential oil, distilled water is given to mothers.

##### Participants/Inclusion and exclusion criteria

Nulliparous or multi gaviid one to three; age between 18-18 years old; education in reading and writing; pregnancy age between 40-38 weeks; live embryo; single, ceramic display and without abnormalities; fetal weight between 4000-2500 g; uterine contractions spontaneously; cervical dilatation 5-4 cm; healthy embryonic embryos; no clear pelvic stenosis; fetal heart rate in the normal range; lack of a history of diseases such as heart disease, diabetes, .....; no history of pregnancy problems and complications such as hypertension, preeclampsia ...; no history of mental disorders; no addiction to drugs; absence of cesarean section or stimulation of labor pains; lack of olfactory problems and sensitivity to herbal medicines, not taking certain medications.

##### Intervention groups

Giving spring orange essential oil to participants in the

intervention group and giving distilled water to research units in the control group.

##### Main outcome variables

The severity of labor pains and childbirth satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190123042469N2**

Registration date: **2020-06-13, 1399/03/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-13, 1399/03/24**

Update count: **0**

##### Registration date

2020-06-13, 1399/03/24

##### Registrant information

##### Name

Sedighesadat Kazeminia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4467 1441

##### Email address

kazemigh60@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-22, 1399/03/02

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of citrus aurantium essential oil on the severity of pain in the first and second stages of labor and childbirth Satisfaction with delivery in primegravid women

**Public title**  
The effect of spring orange essential oil on the severity of pain and maternity satisfaction

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Nulliparous or Multi Gravid are one to three The age should be between 35-18 years. Pregnancy based on early pregnancy or LMP ultrasound between 40-38 weeks. The weight of the fetus should be between 4000-2500 grams according to Johnson's law. The uterine contractions have started automatically. Alternate every 5 to 10 minutes and the duration is 20 to 35 seconds. Cervical dilatation should be 5-4 cm. The fetal membranes are healthy or if the rupture of the mammals is not more than 12 hours after the rupture of the mammals. It should not be obvious in the examination of pelvic stenosis. The fetal heart rate should be in the normal range and there should be no abnormal pattern of heart rate. History of diseases such as heart disease, diabetes, hypertension, name, anemia, hepatitis No history of pregnancy problems and complications such as hypertension, preeclampsia, no threat of miscarriage. No history of mental disorders. Odor problems and sensitivity to herbal medicines, do not have perfumes according to the person's opinion. Do not take any special medicine.  
**Exclusion criteria:**  
Prohibited for normal delivery

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

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Research units are not informed of their placement in one of the study groups.

**Placebo**

Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Gonabad University of Medical Sciences  
**Street address**  
Imam Street, Gonabad University of Medical Sciences  
**City**  
Gonabad  
**Province**  
Razavi Khorasan  
**Postal code**  
9691793718  
**Approval date**  
2020-01-27, 1398/11/07  
**Ethics committee reference number**  
IR.GMU.REC.1398.151

## Health conditions studied

**1**

**Description of health condition studied**  
The severity of pain and the satisfaction of childbirth

**ICD-10 code**  
O60-75

**ICD-10 code description**  
Complications of labour and delivery

## Primary outcomes

**1**

**Description**  
The severity of labor pains

**Timepoint**  
From the beginning of the active phase of labor until the end of the second stage of labor

**Method of measurement**  
Visual scale of pain

**2**

**Description**  
Childbirth Satisfaction

**Timepoint**  
6 hours after delivery

**Method of measurement**  
McKay Satisfaction Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: From the beginning of the active phase of delivery until the end of the second stage of delivery in the intervention group, 4 ml of spring orange essential oil is poured on the absorbable handkerchief, smells and is the same size and is attached to the collar of their clothes with a pin.

#### Category

Treatment - Other

### 2

#### Description

Control group: From the beginning of the active phase of delivery until the end of the second stage of delivery in the intervention group, 4 ml of distilled water is poured on the non-absorbable, odorless and one-size-fits-all handkerchief and attached to the collar of their clothes with a pin Is replaced.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Allameh Behloul Gonabadi Hospital

##### Full name of responsible person

Narges Bahri

##### Street address

Imam Street, Gonabad University of Medical Sciences

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 5027

##### Email

nargesbahri@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gonabad University of Medical Sciences

##### Full name of responsible person

Javad Bazeli

##### Street address

Imam Street, Gonabad University of Medical Sciences

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 5027

##### Email

Riasat@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

Narges Bahri

##### Position

Associate Professor of Gonabad University of Medical Sciences

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

##### Street address

Imam Street, Gonabad University of Medical Sciences

##### City

Gonabad

##### Province

Razavi Khorasan

##### Postal code

9691793718

##### Phone

+98 51 5722 5027

##### Email

nargesbahri@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Gonabad University of Medical Sciences

**Full name of responsible person**

Narjes Bahri

**Position**

Associate Professor of Gonabad University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Imam Street, Gonabad University of Medical Sciences

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

397

**Phone**

+98 51 5722 5027

**Email**

nargesbahri@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Narjes Bahri

**Position**

Associate Professor of Gonabad University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Imam Street, Gonabad University of Medical Sciences

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

۹۶۹۱۷۹۳۷۱۸

**Phone**

+98 51 5722 5027

**Email**

nargesbahri@yahoo.com

**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**

No more information

**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