

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparative study of bicarbonate oral intake and infusion of oxytocin versus infusion of oxytocin alone on resolving the labor active phase dystocia in primiparous women

#### Protocol summary

##### Study aim

Comparison of bicarbonate oral intake and infusion of oxytocin versus infusion of oxytocin alone on resolving the labor active phase dystocia in primiparous women

##### Design

clinical trial

##### Settings and conduct

The target population included all nulliparous women admitted to maternity wards of the Jiroft University of Medical Sciences for delivery and they have the entry criteria of the study. Intervention group will use oral bicarbonate as 4.26 g of sodium bicarbonate. Each pack of oral bicarbonate is taken in a glass containing 200 cc of water. In the control group, without Prescribing of bicarbonate induction continues and The Pareto graph form is completed by the midwife until the end of the third stage of labor.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: nulliparity, gestational age of 42-37 weeks, entry into active phase of labor, absence of known fetal complications, fetal macrosomia and severe pre-eclampsia in the mother, A cephalic presentation and labor is stopped according to the partogram pattern (stopping dilatation for one hour) In women who are being induced. Exclusion criteria: the mother's regret to cooperate at each stage of the study

##### Intervention groups

Primiparous women with the labor active phase dystocia for one hour or more

##### Main outcome variables

Duration of the first and second stages of labor, type of delivery, Apgar score

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20181219042051N2**

Registration date: **2019-05-16, 1398/02/26**

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

Last update: **2019-05-16, 1398/02/26**

Update count: **0**

#### Registration date

2019-05-16, 1398/02/26

#### Registrant information

##### Name

Zohreh Ghorashi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3425 5900

##### Email address

zghorashi@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-01-20, 1397/10/30

#### Expected recruitment end date

2019-06-04, 1398/03/14

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparative study of bicarbonate oral intake and infusion of oxytocin versus infusion of oxytocin alone on

resolving the labor active phase dystocia in primiparous women

#### Public title

The effect of bicarbonate oral intake and infusion of oxytocin on resolving the labor active phase dystocia

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Primigravidity, gestational age of 37-42 weeks, entry into active phase, absence of known fetal complications and macrosomia, absence of severe pre-eclampsia in the mother, Cephalic presentation with a single pregnancy and labor is stopped according to the partogram pattern (stopping dilatation for one hour). gestational age of 37-42 weeks entry into active phase absence of known fetal complications absence of macrosomia absence of severe pre-eclampsia Cephalic presentation single pregnancy labor is stopped according to the partogram pattern (stopping dilatation for at least one hour) In women who are being induced

##### Exclusion criteria:

Exclusion criteria: The mother's regret to cooperate at each stage of the study

#### Age

No age limit

#### Gender

Female

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: **142**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

National Ethics Committee for Biomedical Research

###### Street address

Parastar Street, School of nursing midwifery

###### City

Rafsanjan

#### Province

Kerman

#### Postal code

7718796755

#### Approval date

2019-01-11, 1397/10/21

#### Ethics committee reference number

IR.RUMS.REC.1397.182

### Health conditions studied

#### 1

##### Description of health condition studied

The labor active phase dystocia

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

Dilatation progress

##### Timepoint

Every hour in active phase

##### Method of measurement

Vaginal examination

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Drinking oral bicarbonate solution and oxytocin infusion after disticia. Each pack of bicarbonate contains 4.26g of sodium bicarbonate that mixed in 200 cc water in a glass and it will be drank by eligible women within a few minutes . Sodium bicarbonate with NaHCO<sub>3</sub> formula has been purchased from the German company (Merck).

##### Category

Treatment - Other

#### 2

##### Description

Control group: without Prescribing of bicarbonate, induction continues and The Pareto graph form is completed by the midwife until the end of the third stage of labor.

##### Category

Other

### Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

The Maternity Wards covered by Jiroft University of Medical Sciences

**Full name of responsible person**

Mitra Seyedinejad

**Street address**

Modares

**City**

Jiroft

**Province**

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**Postal code**

7861735133

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+98 34 4321 0264

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mitraseyedi42@gmail.com

### Sponsors / Funding sources

## 1

#### Sponsor

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Zohreh Ghorashi

**Street address**

School of nursing midwifery, Parastar Street, Rafasanjan, Iran

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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**

Rafsanjan 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**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

zohreh ghorashi

**Position**

Assistant proffesor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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### Person responsible for scientific inquiries

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**Position**

Assistant professor

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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**

Not applicable

**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