

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 NaHCO₃ 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Zohreh Ghorashi

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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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Latest degree

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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