

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of normal saline solution and dextrose saline infusion on duration of active phase and second stage of labor in nulliparous women

Protocol summary

Summary

Objective: Comparison of normal saline solution and dextrose saline infusion on duration of active phase and second stage of labor in nulliparous women. Materials and Methods: In this randomized clinical trial 150 eligible pregnant women presenting with labor pain were randomly divided into two groups. Inclusion criteria: gestational age 36 weeks or more; nulliparity; singleton; cephalic presentation; cervical dilatation 3-5 cm (active phase of labor). Exclusion criteria : diabetes; preeclampsia; cardiac or kidney diseases; intrauterine fetal death; chorioamnionitis; meconium in amniotic fluid; fetal distress. One group received normal saline and the other dextrose saline 5% administered at a rate of 120cc/h. Initial vaginal examination and onset of serum administration was recorded for each patient. Thereafter examination was done every hour and the results were recorded. If the dilatation progress was less than 1.2 cm per hour, uterine contractions was assessed and if inappropriate, oxytocin at a dose of 10unit/liter serum was administered. In case of no change in dilatation for 2 hours or descend for 1 hour the patient was scheduled for c/s. If labor progressed at a normal pace, the time of complete dilation , duration of second stage of labor , Apgar scores were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209253025N3**

Registration date: **2014-02-21, 1392/12/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-21, 1392/12/02

Registrant information

Name

Farideh Movahed

Name of organization / entity

Qazvin University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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+98 28 1335 0307

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Qazvin University Of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of normal saline solution and dextrose saline infusion on duration of active phase and second stage of labor in nulliparous women

Public title

Comparison of normal saline solution and dextrose saline infusion on duration of active phase and second stage of labor in nulliparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: gestational age 36 weeks or more; nulliparity; singleton; cephalic presentation; cervical dilatation 3-5 cm (active phase of labor). Exclusion criteria: diabetes; preeclampsia; cardiac or kidney diseases; intrauterine fetal death; chorioamnionitis; meconium in amniotic fluid; fetal distress.

Age

From **16 years** old to **44 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Qazvin University Of Medical Sciences

Street address

Bahonar Blvd

City

Qazvin

Postal code

Approval date

2013-09-04, 1392/06/13

Ethics committee reference number

7777/20/28

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

Single spo

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

Duration of active phase of labor

Timepoint

Vaginal examination : bigining of active phase (cervical dilatation 3-5 cm) , time of full dilatation (10 cm)

Method of measurement

Minute

2

Description

Duration of second phase of labor

Timepoint

Time of full dilatation until expulsion of fetus

Method of measurement

Minute

Secondary outcomes

1

Description

Apgar score

Timepoint

First Minute, minute 5 after birth

Method of measurement

Apgar tab

Intervention groups

1

Description

Infusion of normal saline 120 cc/h in active phase of labor

Category

Treatment - Drugs

2

Description

Infusion of dextrose saline 5% 120cc/h in active phase of labor

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Farideh Movahed

Street address

Kosar Hospita, Taleghni street, Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor For Research of Qazvin University of
Medical Science

Full name of responsible person

Dr Saeed Assefzadeh

Street address

Bahonar Blvd, Qazvin

City

Qazvin

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-Chancellor For Research of Qazvin University of
Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Qazvin University of Medical Science

Full name of responsible person

Dr Farideh Movahed

Position

Obstetrician & Gynecologist / Associated professor

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty