Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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; intrauterian fetal death; chorioamnionitis; meconium in amniotic fluid; fetal distress. One group received normal saline and the other dextrose saline 5% administrated 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 administrated. 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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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; intrauterian 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 salin 120 cc/h in active phase of labor

Category
Treatment - Drugs

2

Description
Infusion of dexterose 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
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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