

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparing parenteral 5% dextrose, ringer and oral intake on the duration of labor stages in nulliparous women: A double- blinded randomized, controlled trial

Protocol summary

Summary

The present study aims to determine the effects of intravenous dextrose 5%, Ringer and oral fluids on the courses of labor. This double-blind (investigators-participants) randomized controlled trial will be conducted in three groups of 201 nulliparous women referring to Mahabad Emam-Khomeini Hospital. Eligibility criteria will include: being nulliparous, term pregnancy (gestational age 38-41 weeks), singleton pregnancy with cephalic presentation, spontaneous onset of delivery and in active phase of labor. Exclusion criteria include the following: women with labor induction, the ones with high risk pregnancy, and intrauterine fetal death. Intervention: The women in the first group will receive intravenous dextrose 5% while the other two groups will respectively receive Ringer with oral fluids and oral fluids only. The serum intravenous infusion rate will be 125 ml/h since admission to delivery room until 2 hours postpartum. The primary outcomes: duration of first, second and third stages of labor. The secondary outcomes: maternal (type of delivery, frequency of oxytocin administration, frequency of prolonged labor) and neonatal (Apgar scores) outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602213027N35**
Registration date: **2016-03-13, 1394/12/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

Name

Fahimeh Sehhatie Shafaie

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

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sehhatief@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-06-09, 1395/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing parenteral 5% dextrose, ringer and oral intake on the duration of labor stages in nulliparous women: A double- blinded randomized, controlled trial

Public title

Effects of intravenous dextrose 5% on delivery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: being nulliparous, ages 18-35, gestational age (38-41 weeks), singleton pregnancy with

cephalic presentation, onset of first stage of labor and 3-4 cm dilated, spontaneous onset of labor, maternal first trimester body mass index 18.5 <BMI<24.9 kg/m², normal maternal pelvis (according to the experts and the researchers examinations), clinical and ultrasound prediction of no fetal macrosomia (weight more than 4.5 kg). Exclusion criteria: women with labor induction (indications of induction of labor such as prolonged rupture of membranes (over 18 h), gestational hypertension, nonreassuring fetal status, diabetes or preeclampsia), high risk pregnancies (gestational diabetes, preeclampsia, heart or kidney diseases, IUGR, detachment or placenta praevia, . . .) evidence of chorioamnionitis (maternal fever over 38oc) and fetal distress (abnormal NST), intrauterine fetal death, use of epidural

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **201**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

tabriz university of medical sciences

Street address

Central building, Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Postal code**Approval date**

2016-01-18, 1394/10/28

Ethics committee reference number

TBZMED.REC.1394.972

Health conditions studied**1****Description of health condition studied**

Delivery

ICD-10 code

XV

ICD-10 code description

O80-O84

Primary outcomes**1****Description**

Total of first stage of delivery

Timepoint

Since intervention to full dilatation

Method of measurement

Timer

2**Description**

Total of Second stage of delivery

Timepoint

Full Dilatation to delivery

Method of measurement

Timer

3**Description**

Total of Third stage of delivery

Timepoint

From birth to Exit placenta

Method of measurement

Timer

Secondary outcomes**1****Description**

Maternal outcomes (delivery type, frequency of use of oxytocin, the frequency of prolonged labor)

Timepoint

Start deliveries until the end of maternity

Method of measurement

check list

2**Description**

Neonatal outcome (Apgar score)

Timepoint

Immediately after delivery

Method of measurement

check list

Intervention groups

1

Description

5% dextrose injection experimental group serum: serum administered dextrose 5% at a speed of 125 ml per hour in nulliparous women with vaginal delivery

Category

Treatment - Drugs

2

Description

The intervention group injected Ringer: Ringer prescribed speed of 125 ml per hour in nulliparous women with vaginal delivery

Category

Treatment - Drugs

3

Description

The control group received only oral liquid

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital in the city of Mahabad

Full name of responsible person

Fatemeh Ahadi yulgunlu

Street address

Imam Khomeini Hospital, Boulevard martyr
Abdollahnejad, Western Azerbaijan

City

Mahabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

doc Mohammad Reza Rashidi

Street address

Center building of Tabriz Medical University, Golgasht
Street, Azadi Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

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

Farzane Shahmohammadi

Full name of responsible person

Fatemeh Ahadi Yulgunlu

Position

faculty of midwifery student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Medical and sciences of tabriz universcity

Full name of responsible person

Fahime Sehhatie Shaffaee

Position

Master degree

Other areas of specialty/work

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Position

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Web page address**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