

# 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)

##### Phone

+98 41 1479 6770

##### Email address

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/m<sup>2</sup>, 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

##### Street address

Emam Street - City chaharborg

##### City

chaharborg

##### Postal code

##### Phone

+98 44 4532 2868

##### Fax

##### Email

fatemehahadi8@gmail.com

##### Web page address

## 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

##### Street address

blinding of Medical and Sciences University, Southern  
Shriati Street, Tabriz

##### City

Tabriz

##### Postal code

##### Phone

+98 41 3477 0648

##### Fax

##### Email

sehhatief@tbzmed.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Medical and Sciences of Tabriz

**Full name of responsible person**

Fahime Sehhatie Shafae

**Position**

Master degree

**Other areas of specialty/work****Street address**

Bilding of Medical and Sciences University South  
Shariati, Tabriz

**City**

Tabriz

**Postal code****Phone**

+98 41 3477 0648

**Fax****Email**

sehhatief@tbzmed.ac.ir

**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*