

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### the effect of increased intravenous hydration on duration of labor and type of delivery

#### Protocol summary

##### Summary

Background: Restriction received food and fluid in women during Labor has a side effect on uterine contractions. The aim of the present study was determined the effect of increased intravenous fluids the duration and type of delivery in nulliparous women. Methods: This is a randomized, single-blind clinical trial study that was performed at the Ilam Mustafa Khomeini Hospital of Ilam, Iran in 2010. Through a randomized single blind controlled clinical trial, 120 full-term, nulliparous women with uncomplicated singleton pregnancies were randomly assigned to receive lactated ringers at 60,120 and 240 ml/ hour (IV fluid group) throughout active labor or usual care. The groups were matched and all women were allowed unrestricted oral fluids consumption. The process of labor, cervical dilatation and descent were recorded after each examination by trained midwives . Type of delivery was recorded . After collecting, the results were analyzed by spss software. Inclusion criteria: Iranian nationality; 35-18 years of age ; primiparous, singleton pregnancy; gestational age 38-40; without CPD; optimal care during pregnancy; blood pressure less than 140/90 mmHg; body mass index 19/8-26(kg m) before pregnancy; beginning of the active phase of labor with cervical dilatation 4 cm ; intact of membran ; estimated fetal weight less than 4000 grams; Excluding criteria : Polyhydramnios; abnormal presentation; preeclampsia; pyelonephritis ; any other febrile illnesses in the last 48 hours; known medical conditions before and during pregnancy such as asthma; cardiovascular disease; diabetes; kidney disease or cratinin more than 1 at the admission time; disorders of gastroenteritis during the last 48 hours; symptoms of dehydration in the last 48 hours

#### General information

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201105256575N2**

Registration date: **2011-07-16, 1390/04/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2011-07-16, 1390/04/25

#### Registrant information

##### Name

Ashraf Direkvand-Moghadam

##### Name of organization / entity

Ilam University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 84 3222 7134

##### Email address

direkvand-a@medilam.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Ilam University of Medical Sciences

#### Expected recruitment start date

2008-09-22, 1387/07/01

#### Expected recruitment end date

2009-09-23, 1388/07/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

the effect of increased intravenous hydration on duration

of labor and type of delivery

### Public title

The effect of increased intravenous hydration on the course and outcome of labor in nulliparous women during 1387.

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: Iranian nationality; 35-18 years of age; primiparous, singleton pregnancy; gestational age 38-40; without CPD; optimal care during pregnancy; blood pressure less than 140/90 mmHg; body mass index 19/8-26(kg m) before pregnancy; beginning of the active phase of labor with cervical dilatation 4 cm; intact of membranes; estimated fetal weight less than 4000 grams; Excluding criteria: Polyhydramnios; abnormal presentation; preeclampsia; pyelonephritis; any other febrile illnesses in the last 48 hours; known medical conditions before and during pregnancy such as asthma; cardiovascular disease; diabetes; kidney disease or creatinine more than 1 at the admission time; disorders of gastroenteritis during the last 48 hours; symptoms of dehydration in the last 48 hours

### Age

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

### Gender

Female

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

### 1

#### Registry name

#### Secondary trial Id

#### Registration date

2017-11-21, 1396/08/30

## Ethics committees

### 1

#### Ethics committee

### Name of ethics committee

Ethics committee Ilam University of Medical Sciences

### Street address

Ilam University of Medical Sciences, Ilam, Iran

### City

Ilam

### Postal code

### Approval date

2009-05-17, 1388/02/27

### Ethics committee reference number

1803/40/22

## Health conditions studied

### 1

#### Description of health condition studied

Increased Intravenous Hydration of Nulliparous in Labor

#### ICD-10 code

o80

#### ICD-10 code description

Single spontaneous delivery

## Primary outcomes

### 1

#### Description

duration of labor

#### Timepoint

start of active phase to 24h after delivery

#### Method of measurement

duration of labor according to minute

## Secondary outcomes

### 1

#### Description

type of delivery

#### Timepoint

type of delivery

#### Method of measurement

type of delivery vaginal or cesarean

## Intervention groups

### 1

#### Description

The second, group received 60 ml of lactated Ringer's solution IV per hour

#### Category

Treatment - Drugs

### 2

#### Description

The first group (usual care) received lactated Ringer's solution IV per hour whenever they needed based on obstetrical condition.

**Category**

Treatment - Drugs

**3****Description**

The third group received 120 ml of lactated Ringer's solution IV per hour

**Category**

Treatment - Drugs

**4****Description**

The fourth group received 240 ml of lactated Ringer's solution IV per hour

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mustafa Khomeini hospital, Ilam

**Full name of responsible person**

BA of Midwifery

**Street address**

Mustafa Khomeini hospital, Ilam , Iran

**City**

Ilam

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Ilam University of Medical Sciences

**Full name of responsible person**

Dr Afra Khosravi research manager of research, Ilam University of Medical Sciences

**Street address**

Vice chancellor for research Ilam University of Medical Sciences, Pajuhesh Avenue, Bangnjab, Ilam

**City**

Ilam

**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, Ilam 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**

Department of Midwifery, Faculty of Nursing and Midwifery, Ilam University of Medical Sciences

**Full name of responsible person**

Ashraf Direkvand-Moghadam

**Position**

MSc of Midwifery

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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*