

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Assessment of oral glucose solution & maternal abdominal palpation effect on fetal non stress test.

#### Protocol summary

##### Study aim

Comparison of the effects of oral glucose solution or maternal abdominal palpation on non stress test.

##### Design

A randomized clinical trial, with two intervention groups of 150 pregnant women, between November 2018 to September 2019.

##### Settings and conduct

At Fatemieh Hospital in Hamadan city, under the same conditions as the rest in a quiet room, left lateral position, and empty bladder, the research units after completion of the consent form, are randomly divided into 3 groups (Three groups of 50 people), in one group administration of 50g/250cc of water and in another group, the abdominal palpation of the mother (Leopold maneuver) is carried out in one or two times and the movements of the fetus are graded ( If there is no movement, zero score, if the mother feels the movements of the fetus, score 1, if the examiner feels the movements of the fetus score 2 and if the examiner sees the movements of the fetus score 3, then score 2 or 3 are selected). Non Stress Test for 20 minutes along with cardiac monitoring, movements and fetal heart rate is recorded. One group is also checked with no intervention as a control group.

##### Participants/Inclusion and exclusion criteria

- Age 18 to 35 - Gestational age 34 to 41 weeks - Single pregnancy - No history of infertility - regular pregnancy care - Not any illness in pregnancy (diabetes, blood pressure and ...) - normal glucose tolerance test at 28-24 weeks of gestation - No smoking - No infection of Hydramnios, Intrauterine death and ... - No recognize congenital anomalies of the fetus - Not use narcotics, opiates or other drugs by the mother

##### Intervention groups

The research units were randomly divided into two groups, one group administered 50 grams of oral sugars in 250 cc of water and in the other group, the abdominal palpation of the Leopold maneuvered, one or two times

with 10 minutes interval, is done.

##### Main outcome variables

Fetal movement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012082110635N1**

Registration date: **2012-12-31, 1391/10/11**

Registration timing: **prospective**

Last update: **2018-12-15, 1397/09/24**

Update count: **2**

##### Registration date

2012-12-31, 1391/10/11

##### Registrant information

##### Name

Soodabeh Aghababaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3838 0150

##### Email address

aghababaii@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for Research and Technology Research, Hamadan medical university of Iran.

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Assessment of oral glucose solution & maternal abdominal palpation effect on fetal non stress test.

**Public title**  
Assessment of oral glucose solution & maternal abdominal palpation effect on fetal non stress test.

**Purpose**  
Diagnostic

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age 18 to 35 years old Gestational age 34 to 41 weeks Single pregnancy Infertility failure Having regular pregnancy care The absence of any illness in pregnancy (diabetes, blood pressure and ...) Having a normal glucose tolerance test at 28-24 weeks of gestation No smoking No Hydramnios and Intrauterine death no recognize congenital anomalies of the fetus to Do not use narcotics, opiates or other drugs by the mother

**Exclusion criteria:**  
abnormal fetal heart rate

**Age**  
To 35 years old

**Gender**  
Female

**Phase**  
2-3

**Groups that have been masked**  

- Data analyser

**Sample size**  
Target sample size: 150

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Research units are randomly assigned to one of two study groups using random numbers and each group receives one of the relevant interventions.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Single blind, data analyzer will be blind.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hamadan Medical university of Iran

##### Street address

Hamadan Medical university; Shahid Fahmideh Ave; Hamadan; Iran.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

65178

##### Approval date

2018-10-13, 1397/07/21

##### Ethics committee reference number

IR.UMSHA.REC.1397.477

## Health conditions studied

### 1

#### Description of health condition studied

Non Stress Test

#### ICD-10 code

O68.9

#### ICD-10 code description

Labour and delivery complicated by fetal stress, unspecified

## Primary outcomes

### 1

#### Description

fetal movement

#### Timepoint

20 minutes after ingestion of 50g of glucose in 250ml of water or Immediately after maternal abdominal palpation.

#### Method of measurement

fetal non stress test

### 2

#### Description

Fetal heart rate

#### Timepoint

20 minutes after ingestion of 50g of glucose in 250ml of water or Immediately after maternal abdominal palpation.

#### Method of measurement

fetal non stress test

## Secondary outcomes

### 1

#### Description

Increase fetal heart rate

**Timepoint**

At the time of testing

**Method of measurement**

Fetal heart rate monitoring

**Intervention groups****1****Description**

All pregnant women will assess in the same conditions, such as same quiet room and semi recumbent position. Women with non reactive NST randomly assign for oral ingestion of 50g of glucose in 250ml of water, then 20 min monitoring will be done after 30 min of intervention.

**Category**

Diagnosis

**2****Description**

All pregnant women will assess in the same conditions, such as same quiet room and semi recumbent position. Women with non reactive NST randomly selected for 1 or 2 times abdominal palpation such as Leopold maneuver with 10 min interval, then 20 min monitoring will be done immediately after intervention.

**Category**

Diagnosis

**3****Description**

Control group:

**Category**

Diagnosis

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

Hamadan Fathemieh Hospital

**Full name of responsible person**

Aghababaei Soodabeh

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Nursing & Midwifery Faculty; Hamadan Medical university; Shahid Fahmideh Ave; Hamadan; Iran.

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

Vice Chancellor for Research and Thecnology Research, Hamadan university of Medical Sciences

**Full name of responsible person**

Dr Said Bashirian

**Street address**

Vice Chancellor for Research and Thecnology Research; Hamadan Medical university; Shahid Fahmideh Ave; Hamadan; Iran.

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info.research@umsha.ac.ir

**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 and Thecnology Research, Hamadan university of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

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

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Nursing & Midwifery Faculty; Hamadan Medical university of Iran.

**Full name of responsible person**

Aghababaei Soodabeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

بهداشت باروری

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Full name of responsible person**

Aghababaei Soodabeh

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data**

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Hamadan Medical university of Iran

**Full name of responsible person**

Soodabeh Aghababaei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

-

**When the data will become available and for how long**

-

**To whom data/document is available**

-

**Under which criteria data/document could be used**

-

**From where data/document is obtainable**

-

**What processes are involved for a request to access data/document**

-

**Comments**

-