

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 Fatemeh 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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

65187

Phone

+98 81 3838 0150

Email

aghababaii@yahoo.com

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.

City

Hamadan

Province

Hamadan

Postal code

65187

Phone

+98 81 3838 0717

Fax

+98 81 3838 0130

Email

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

Street address

Nursing & Midwifery Faculty; Hamadan Medical

university; Shahid Fahmideh Ave; Hamadan; Iran.

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Fax

+98 81 3838 0447

Email

aghababaii@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan Medical university of Iran

Full name of responsible person

Aghababaei Soodabeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

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

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Fax

+98 81 3838 0447

Email

aghababaei@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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

Street address

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

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Phone

+98 81 3838 0535

Fax

+98 81 3838 0447

Email

aghababaei@umsha.ac.ir

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

-