

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigation on effect of prenatal fetal surveillance on neonatal outcomes in diabetic pregnant patients: a diagnostic trial

Protocol summary

Study aim

Evaluation of the effect of prenatal fetal surveillance program in diabetic pregnant patients on neonatal outcomes

Design

A parallel open-label randomized trial on 110 patients. Randomization was one using simple randomization of sealedenvelope.com website software.

Settings and conduct

Eligible diabetic pregnant mothers referred to Imam Khomeini Hospital Complex in Tehran were randomly divided into two groups of 55, and underwent one of the two methods of prenatal care, NST and BPP. Their neonatal outcomes were compared after delivery. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic pregnant patients who receive oral medication or insulin therapy, gestational age > 28w, Exclusion Criteria: Another chronic disease, vascular complications of diabetes, corticosteroid use.

Intervention groups

Intervention group 1: Diabetic pregnant mothers under medical treatment for more than 28 weeks who are examined with non-stress test (NST). Intervention group 2: Diabetic pregnant mothers under medical treatment for more than 28 weeks who are examined with biophysical profile (BPP). they take.

Main outcome variables

Newborn weight, newborn baby, fifth minute Apgar, incidence of hypoglycemia, hospitalization in the neonatal intensive care unit (NICU).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046278N1**

Registration date: **2023-08-25, 1402/06/03**

Registration timing: **retrospective**

Last update: **2023-08-25, 1402/06/03**

Update count: **0**

Registration date

2023-08-25, 1402/06/03

Registrant information

Name

Zeinab Mansouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8825 8519

Email address

z_mansouri88@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-11, 1400/07/19

Expected recruitment end date

2021-12-30, 1400/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on effect of prenatal fetal surveillance on neonatal outcomes in diabetic pregnant patients: a diagnostic trial

Public title

Effect of prenatal fetal surveillance on neonatal outcomes in diabetic pregnant patients

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetic pregnant patients who receive oral medication or insulin therapy Gestational age > 28 weeks Consent to participate

Exclusion criteria:

History of chronic diseases, including endocrine diseases (Except diabetes) History of corticosteroid use Vascular complications of diabetes

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 110

Randomization (investigator's opinion)

Randomized

Randomization description

Using the software of sealedenvelope.com and simple randomization method, a random sequence containing 55 code A and 55 code B was generated and informed to the researcher one by one by a third person independent of the study.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of tehran university of medical sciences

Street address

Tehran University of Medical Sciences central Building, Qods St. Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1448934469

Approval date

2020-10-13, 1399/07/22

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.285

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

Diabetes in pregnancy

ICD-10 code

O24

ICD-10 code description

Diabetes mellitus in pregnancy

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

5th minute apgar score

Timepoint

after birth

Method of measurement

examination

2**Description**

Admission to neonatal intensive care unit (NICU)

Timepoint

1 months after birth

Method of measurement

Clinical Records

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

Birth weight

Timepoint

After birth

Method of measurement

Weight scale

2**Description**

Birth height

Timepoint

After birth

Method of measurement

Meter

3**Description**

Macrosomia Incidence

Timepoint

After birth

Method of measurement

Physical exam

4

Description

Incidence of small for gestational age (SGA)

Timepoint

After birth

Method of measurement

Physical exam

5

Description

Hypoglycemia incidence

Timepoint

After birth

Method of measurement

Lab test

6

Description

Hyperbilirubinemia incidence

Timepoint

After birth

Method of measurement

Lab test

Intervention groups

1

Description

Biophysical intervention group: Patients will be subjected to weekly biophysical evaluation after 36 weeks. In this method, fetal movement, fetal breathing, and amniotic fluid volume are measured through ultrasound.

Category

Diagnosis

2

Description

NST intervention group: Patients will undergo a weekly non-stress test (NST) from the 36th week of pregnancy. In this method, the fetal heart rate is monitored through the cardiograph device in the states with and without fetal contractions.

Category

Diagnosis

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam khomeini hospital complex

Full name of responsible person

Zeinab Mansouri

Street address

End of Keshavarz Boulevard,

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z_mansouri88@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

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1417653761

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afotouhi@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Mansouri

Position

Resident of obstetrics & gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Imam khomeini hospital complex, End of Keshavarz
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fahimeh Ghotbizadeh Vahdani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Mansouri

Position

Resident of obstetrics & gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Fax**Email**

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

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available