Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 recieve oral medication or insulin therapy Gestational age> 28weeks 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 committe of tehran university of medical sciences
Street address
Tehran University of Medical Sceinces central Building, Qods St. Keshavarz Boulvard
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 Boulvard,
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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 Boulvard,
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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

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Resident of obstetrics & gynecology
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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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