

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

To compare the maternal, fetal and cost-effectiveness outcomes in 5 different screening strategies for gestational diabetes among pregnant women with ≤ 14 weeks of gestation

Protocol summary

Summary

The aim of the present study is to evaluate the cost effectiveness, maternal and fetal outcomes in different screening strategies of gestational diabetes (GDM). This study is a randomized control trial. A total of 39500 pregnant women at first trimester of pregnancy from selected cities among 5 provinces of Yazd, Khorasan, south Kordestan, Golestan and Bushehr will be recruited to the study and 5 screening strategies for gestational diabetes will be allocated between them. These strategies are: Protocol A: the first pregnancy trimester GDM screening method is fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will receive standard treatment for GDM. If those women do not affected by GDM in the 1th screening test, they will be invited for 2ed trimester of GDM screening at 24-28 weeks of gestations by one step approach with OGTT -75 g Glucose. It will be considered as GDM, if two abnormal test will be detected. Protocol B: the first pregnancy trimester GDM screening method is fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will not receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by one step approach with OGTT -75 g Glucose. It will be considered as GDM, if two abnormal test will be detected. Protocol C: the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will not receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by one step approach with OGTT -75 g Glucose. It will be considered as GDM, if one abnormal test detect. Protocol D: the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild

gestational diabetes will receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by two step approach with OGTT -100 g Glucose. It will be considered as GDM, if two abnormal test detect. Protocol E: the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will not receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by two step approach with OGTT -100 g Glucose. It will be considered as GDM, if two abnormal test detect. Exclusion criteria of present study is Preexisting diabetes; Prior gestational diabetes; A history of stillbirth; Multifetal gestation; Asthma; Chronic hypertension; Taking corticosteroids. At the end the maternal, fetal and cost effectiveness outcomes will compare between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707081281N1**

Registration date: **2017-02-15, 1395/11/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-15, 1395/11/27

Registrant information

Name

Fahimeh Ramezani Tehrani

Name of organization / entity

Research Institute for Endocrine Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

National institute for medical research development (NIMAD)

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To compare the maternal, fetal and cost-effectiveness outcomes in 5 different screening strategies for gestational diabetes among pregnant women with ≤ 14 weeks of gestation

Public title

Comparison of various protocols for management of gestational diabetes

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: All 1st trimester pregnant women who refer from health centers of selected cities among 5 provinces will recruit to the study Exclusion criteria: Preexisting diabetes; Prior gestational diabetes; A history of stillbirth; Multifetal gestation; Asthma; Chronic hypertension; Taking corticosteroids

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **39500**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

At first, five provinces in the different geographical regions of north, south, east, west and center of the country including Yazd, Khorasan, south Kordestan, Golestan and Bushehr will be invited. The 5 selected cities from each province will be interred to the study. In each province, based on socioeconomic differences the cities will be divided in to two cluster: the center of province and other cities. The 5 protocol will be randomly allocated among cities in this two cluster.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National institute for medical research development

Street address

no.21 West Fatemi

City

Tehran

Postal code

1419169311

Approval date

2016-03-01, 1394/12/11

Ethics committee reference number

IR.NIMAD.REC.1394.013

Health conditions studied

1

Description of health condition studied

Gestational Diabetes

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

Cost of health services including pregnancy, delivery and neonatal period

Timepoint

After expenses in each phase

Method of measurement

View, record and receive expenses factors

2

Description

Quality-adjusted life years (QALYs)

Timepoint

pregnancy, delivery and neonatal period

Method of measurement

Quality-adjusted life years (QALYs)

3

Description

Percentage of birth weight > 90th percentile

Timepoint

at the time of delivery

Method of measurement

Using fetal growth curves

4

Description

Percentage of primary cesarean section

Timepoint

at the time of delivery

Method of measurement

View and registered cases of primary cesarean

5

Description

Percentage of neonatal hypoglycemia

Timepoint

At first hour after birth

Method of measurement

Measurement the blood glucose levels using a laboratory glucose kit

Secondary outcomes

1

Description

Percentage of birth weight < 10th percentile

Timepoint

After delivery

Method of measurement

Using fetal growth curves

2

Description

The percentage of admission to the neonatal intensive care unit

Timepoint

neonatal period (T the time of birth until day 28 after birth)

Method of measurement

Observation and record

3

Description

Birth trauma including fracture of clavicle, brachial plexus injury

Timepoint

At the time of delivery

Method of measurement

Observation and record

4

Description

Still birth (intra uterine death)

Timepoint

delivery

Method of measurement

delivery registry

5

Description

Preeclampsia

Timepoint

2nd and 3rd trimesters

Method of measurement

prenatal records

6

Description

Preterm labor

Timepoint

delivery

Method of measurement

delivery registry

7

Description

Shoulder dystocia

Timepoint

delivery

Method of measurement

delivery registry

8

Description

Neonatal hyperbilirubinemia

Timepoint

neonatal period

Method of measurement

blood bilirubine

9

Description

Neonatal hypocalcaemia

Timepoint

neonatal period

Method of measurement

blood calcium

Intervention groups

1

Description

Protocol A: In this protocol, the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will receive standard treatment. If those women do not

affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by one step approach with OGTT -75 g Glucose. It will be considered as GDM, if one abnormal test detect.

Category

Treatment - Drugs

2

Description

Protocol B: In this protocol, the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will not receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by one step approach with OGTT -75 g Glucose. It will be considered as GDM, if two abnormal test detect.

Category

Treatment - Drugs

3

Description

Protocol C: In this protocol, the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will not receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by one step approach with OGTT -75 g Glucose. It will be considered as GDM, if one abnormal test detect.

Category

Treatment - Drugs

4

Description

Protocol D: In this protocol, the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by two step approach with OGTT -100 g Glucose.

Category

Treatment - Drugs

5

Description

Protocol E: In this protocol, the screening test in first pregnancy trimester will be fasting blood sugar (FBS). In addition, all of women with mild gestational diabetes will not receive standard treatment. If those women do not affected by GDM in the 1th screening test, they will invite for 2ed trimester of GDM screening at 24-28 weeks of gestations by two step approach with OGTT -100 g Glucose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

All urban health centers of Yazd city

Full name of responsible person

Dr. Kalantari

Street address

City

Yazd

2

Recruitment center

Name of recruitment center

All urban health centers of Ardakan city

Full name of responsible person

Dr. Kalantari

Street address

City

Ardakan

3

Recruitment center

Name of recruitment center

All urban health centers of Mehriz city

Full name of responsible person

Dr. Kalantari

Street address

City

Mehriz

4

Recruitment center

Name of recruitment center

All urban health centers of Maybod city

Full name of responsible person

Dr. Kalantari

Street address

City

Maybod

5

Recruitment center

Name of recruitment center

All urban health centers of Bafgh city

Full name of responsible person

Dr. Kalantari

Street address

City

Bafgh

6

Recruitment center

Name of recruitment center

All urban health centers of Baneh city

Full name of responsible person

Dr. Zokaie

Street address**City**

Baneh

7**Recruitment center****Name of recruitment center**

All urban health centers of Bijar city

Full name of responsible person

Dr. Zokaie

Street address**City**

Bijar

8**Recruitment center****Name of recruitment center**

All urban health centers of Dehgolan city

Full name of responsible person

Dr. Zokaie

Street address**City**

Dehgolan

9**Recruitment center****Name of recruitment center**

All urban health centers of Divandare city

Full name of responsible person

Dr. Zokaie

Street address**City**

Divandare

10**Recruitment center****Name of recruitment center**

All urban health centers of Sarvabad city

Full name of responsible person

Dr. Zokaie

Street address**City**

Sarvabad

11**Recruitment center****Name of recruitment center**

All urban health centers of Saghez city

Full name of responsible person

Dr. Zokaie

Street address**City**

Saghez

12**Recruitment center****Name of recruitment center**

All urban health centers of Sanandaj city

Full name of responsible person

Dr. Zokaie

Street address**City**

Sanandaj

13**Recruitment center****Name of recruitment center**

All urban health centers of Ghorve city

Full name of responsible person

Dr. Zokaie

Street address**City**

Ghorve

14**Recruitment center****Name of recruitment center**

All urban health centers of Kamyaran city

Full name of responsible person

Dr. Zokaie

Street address**City**

Kamyaran

15**Recruitment center****Name of recruitment center**

All urban health centers of Marivan city

Full name of responsible person

Dr. Zokaie

Street address**City**

Marivan

16**Recruitment center****Name of recruitment center**

All urban health centers of Boushehr city

Full name of responsible person

Dr. Anaraki

Street address**City**

Boushehr

17**Recruitment center****Name of recruitment center**

All urban health centers of Dashtestan city

Full name of responsible person

Dr. Anaraki

Street address**City**

Dashtestan

18

Recruitment center

Name of recruitment center

All urban health centers of Dashti city

Full name of responsible person

Dr. Anaraki

Street address

City

Dashti

19

Recruitment center

Name of recruitment center

All urban health centers of Genave city

Full name of responsible person

Dr. Anaraki

Street address

City

Genave

20

Recruitment center

Name of recruitment center

All urban health centers of kangan city

Full name of responsible person

Dr. Anaraki

Street address

City

kangan

21

Recruitment center

Name of recruitment center

All urban health centers of Gorgan city

Full name of responsible person

Dr. Kordi

Street address

City

Gorgan

22

Recruitment center

Name of recruitment center

All urban health centers of Aghghela city

Full name of responsible person

Dr. Kordi

Street address

City

Aghghela

23

Recruitment center

Name of recruitment center

All urban health centers of Gonbad city

Full name of responsible person

Dr. Kordi

Street address

City

Gonbad

24

Recruitment center

Name of recruitment center

All urban health centers of v city

Full name of responsible person

Ms. Zamanipour

Street address

City

Birjand

25

Recruitment center

Name of recruitment center

All urban health centers of Gaen city

Full name of responsible person

Ms. Zamanipour

Street address

City

Gaen

26

Recruitment center

Name of recruitment center

All urban health centers of Ferdos city

Full name of responsible person

Ms. Zamanipour

Street address

City

Ferdos

27

Recruitment center

Name of recruitment center

All urban health centers of Tabas city

Full name of responsible person

Ms. Zamanipour

Street address

City

Tabas

28

Recruitment center

Name of recruitment center

All urban health centers of Nehbandan city

Full name of responsible person

Ms. Zamanipour

Street address

City

Nehbandan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National institute for medical research development

Full name of responsible person

Dr. Mesgarpour

Street address

21 Besat Street, Fatemi street

City

Tehran

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

Yes

Title of funding source

National institute for medical research development

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**

Reproductive Endocrinology Research Center
Research Institute for Endocrine Sciences Shahid
Behesht

Full name of responsible person

Fahimeh Ramezani Tehrani

Position

Full Professor, Reproductive Health Fellowship

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Behesht

Full name of responsible person

Fahimeh Ramezani Tehrani

Position

Professor/

Other areas of specialty/work**Street address**

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Web page address

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Research Institute for Endocrine Sciences Shahid
Behesht

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Other areas of specialty/work**Street address**

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City

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Postal code

1985717413

Phone

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Fax**Email**

s.behboudi@hotmail.com

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