Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 one 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

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Name of organization / entity

Research Institute for Endocrine Sciences

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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 protocoles 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
Measurment 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
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Full name of responsible person
Fahimeh Ramezani Tehrani
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Full Professor, Reproductive Health Fellowship
Other areas of specialty/work
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Web page address

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Other areas of specialty/work
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+98 21 2243 2500
Fax
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Web page address

Person responsible for updating data

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Full name of responsible person
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Other areas of specialty/work
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City
Tehran
Postal code
1985717413
Phone
+98 21 2243 2500
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