

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative investigation of pregnancy outcomes among mothers with gestational diabetes using mobile application-assisted remote patient monitoring for blood glucose and mothers receiving conventional care

Protocol summary

Study aim

Comparative investigation of pregnancy outcomes among mothers with gestational diabetes who have been referred to Taleghani hospital, Tehran in the year 2021 using mobile application-assisted remote patient monitoring for blood glucose and mothers receiving conventional care

Design

This study consists of two parallel intervention and control groups without blinding. 75 participants will be recruited through a simple randomization method. 75 participants will be divided into two sets of 25 and 50 people. After that, in excel, 25 'A's and 50 'B's will be written under each other. In the adjacent column, 75 random numbers will be generated using the RAND function. Finally, by sorting both columns by randomly generated numbers, the application of A (Intervention) and B (Control) for each patient will be determined based on her turn of referral.

Settings and conduct

Mothers with GDM who were referred to the Taleghani Hospital will be categorized into intervention and control groups. The remote patient monitoring application will be installed and mothers will have to insert their measured blood glucose at the determined intervals. The variables of the study will be compared between these mothers and the control group.

Participants/Inclusion and exclusion criteria

Inclusion: Pregnancy Age between 18 to 40 years old
Singleton pregnancy
Diagnosis of gestational diabetes mellitus by pregnancy screening tests
Referral to the Taleghani Hospital, Tehran to receive pregnancy care
Possessing a smartphone or tablet at home
Ability to use smartphone applications
Exclusion: Presence of any other underlying disease

Intervention groups

Intervention group: Installing the application and

continuous data record
Control group: conventional care

Main outcome variables

Mother or neonate hypoglycemia, out of control BS, insulin or hospitalization, Apgar, preterm, macrosome, and small/large for gestational age birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170515033984N2**

Registration date: **2021-09-04, 1400/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-04, 1400/06/13**

Update count: **0**

Registration date

2021-09-04, 1400/06/13

Registrant information

Name

Mohsen Abbasi-Kangevari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2201 8583

Email address

mohsen.abbasi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-31, 1400/06/09

Expected recruitment end date

2022-05-30, 1401/03/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigation of pregnancy outcomes among mothers with gestational diabetes using mobile application-assisted remote patient monitoring for blood glucose and mothers receiving conventional care

Public title

Investigation of pregnancy outcomes among mothers with gestational diabetes using mobile application-assisted remote patient monitoring

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnancy Age between 18 to 40 years old Singleton pregnancy Diagnosis of gestational diabetes mellitus (GDM) by pregnancy screening tests Referral to the Taleghani Hospital, Tehran, to receive pregnancy care Possessing smart phone or tablet at home Being able to use smart phone applications

Exclusion criteria:

Presence of any other underlying disease including cardiopulmonary disease Presence of pregnancy complications including placenta previa or pre-eclampsia

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **75****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be applied using the simple method. Indeed, 75 participants will be divided into two sets of 25 and 50 people. After that, in excel, 25 'A's and 50 'B's will be written under each other. In the adjacent column, 75 random numbers will be generated using the RAND function. Finally, by sorting both columns by randomly generated numbers, the application of A (Intervention) and B (Control) for each patient will be determined based on her turn of referral.

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 School of Medicine Shahid Beheshti University of Medical Sciences

Street address

Taleghani Hospital, Shahid E'rabi St, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985711151

Approval date

2021-05-31, 1400/03/10

Ethics committee reference number

IR.SBMU.MSP.REC.1400.137

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

Gestational Diabetes Mellitus

ICD-10 code

O24.4

ICD-10 code description

Gestational diabetes mellitus

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

Occurrence of hypoglycemia in mother

Timepoint

In case of insulin administration four times per day, otherwise, once per day

Method of measurement

Patient files or data extracted from the application database

2**Description**

Occurrence of hypoglycemia in neonate

Timepoint

Once daily

Method of measurement

Patient files or data extracted from the application database

3

Description

number of measured out of control blood sugar

Timepoint

In case of insulin administration four times per day,
otherwise, once per day

Method of measurement

In case of insulin administration four times per day,
otherwise, once per day

4

Description

Insulin administration requirement

Timepoint

per visit with the physician

Method of measurement

Patient files

5

Description

Number of hospitalizations for controlling blood sugar

Timepoint

Per incidence during the study

Method of measurement

پرونده بیمار

6

Description

First minute Apgar score under seven

Timepoint

During delivery

Method of measurement

Patient files

7

Description

Fifth minute Apgar score under seven

Timepoint

During delivery

Method of measurement

Patient files

8

Description

Preterm birth

Timepoint

After birth

Method of measurement

Patient files

9

Description

Macrosomia in new born

Timepoint

After birth

Method of measurement

Patient files

10

Description

Small/large for gestational age

Timepoint

After birth

Method of measurement

Patient files

Secondary outcomes

1

Description

Mother satisfaction with the application

Timepoint

After termination of pregnancy

Method of measurement

Questionnaire

2

Description

Physician and medical staff satisfaction with the
application

Timepoint

After the termination of study

Method of measurement

Questionnaire

3

Description

Patient anxiety

Timepoint

After the termination of study

Method of measurement

PAID-5 Questionnaire

Intervention groups

1

Description

Intervention group: blood sugar measuring device will be provided to this group members and the pertinent mobile application will be installed for them. Mothers under the attendance of the specialist will have to measure their blood sugar on a daily basis and record them. Moreover, the application will do the initial analysis of the data and will warn the patient, her doctor, and her trusted person when needed.

Category

Early detection

2

Description

Control group: they will receive conventional GDM care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Saghar Salehpour

Street address

Taleghani hospital, E'rabi St, Velenjak, Tehran, Iran

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Phone

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taleghani@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Abbasi-Kangevari

Position

Physician

Latest degree

Medical doctor

Other areas of specialty/work

Public Health

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saghar Salehpour

Position

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedighe Hosseini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patients privacy

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