

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Comparison of two teaching methods on pregnancy outcomes in discharge of patients with gestational diabetes

Protocol summary

Summary

It is an experimental study. Objective: To compare the effectiveness of two teaching methods on pregnancy outcomes in discharge of patients with gestational diabetes. Inclusion criteria: 1. Gestational age of 28-36 weeks. 2. Hospitalized due to high blood sugar or gestational diabetes. 3. Failure to attend training classes on diabetes before study entry. 4. Literacy in reading and writing. Exclusion criteria: absence in one of the training sessions. Study: Pregnant women hospitalized due to high blood sugar or diagnosis of gestational diabetes in selected hospitals of Tehran University of Medical Sciences in year 2013. Sample size: A total of 126 people in the availability of hospital admission among women who want to be elected by the inclusion criteria are selected and divided into three groups of 42 subjects (two intervention groups and 1 control group). Intervention: The initial questionnaire will be completed by the researcher for the three groups. The control group will receive routine hospital care. In intervention group 1 in 2 sessions that every session takes 40 minutes in the form of individual or in groups, face to face training will be given in the case of gestational diabetes that the 30 minutes of lecture and 10 minutes will be allotted for questions and answers. In intervention group 2 will distribute the booklet to study their patients. Immediately to 1 month after delivery, the call will be taken by the researcher with patients and record sheet (pregnancy outcomes associated with maternal and fetal pregnancy outcomes) will be completed. Stillbirth cases will be reported.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031812840N1**

Registration date: **2013-04-12, 1392/01/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-12, 1392/01/23

Registrant information

Name

Masoomeh Senobari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4471 1953

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-04-06, 1392/01/17

Expected recruitment end date

2013-09-22, 1392/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of two teaching methods on pregnancy outcomes in discharge of patients with gestational diabetes

Public title

The effect of training on outcomes of gestational diabetes

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion criteria: 1. Gestational age of 28-36 weeks. 2. Hospitalized due to high blood sugar or gestational diabetes. 3. Failure to attend training classes on diabetes before study entry. 4. Literacy in reading and writing. 5. Lack of having any known physical or mental condition that makes training impossible. Exclusion criteria: 1. absence in one of the training sessions. 2. Lack of desire to continue working with research.

Age
 No age limit

Gender
 Female

Phase
 N/A

Groups that have been masked
 No information

Sample size
 Target sample size: **126**

Randomization (investigator's opinion)
 Randomized

Randomization description

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

School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address

Tohid square

City

Tehran

Postal code

1419733171

Approval date

2013-02-13, 1391/11/25

Ethics committee reference number

2967/130/91/5

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

024.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description

Maternal and fetal outcome of gestational diabetes

Timepoint

Immediately to 1 month postpartum

Method of measurement

Self-made recording sheet

Secondary outcomes

1

Description

Reduce costs and improve infant after delivery

Timepoint

Immediately to 1 month postpartum

Method of measurement

Self-made recording sheet

Intervention groups

1

Description

Intervention 1: first initial questionnaire is completed by the researcher. In intervention group 1 in 2 sessions that every session takes 40 minutes in the form of individual or in groups, face to face training will be given in the case of gestational diabetes that the 30 minutes of lecture and 10 minutes will be allotted for questions and answers. Subjects that will be taught in the first sessions include: definition of gestational diabetes, its causes, symptoms, those at risk, control and treatment of gestational diabetes include training on glycemic control, and subjects that will be taught in the second sessions include: Nutrition, physical activity and exercise, insulin, pregnancy follow-up. Immediately to 1 month postpartum, patients will be followed up by the researcher by telephone and record sheet which includes pregnancy outcomes associated with maternal hospitalizations or hospitalization due to maternal gestational diabetes, the number of hospitalizations, number of days of hospitalization, type of delivery, pregnancy-related outcomes such as infant birth weight, gestational age at birth, the first and fifth Apgar score will be complete. Also stillbirth cases will be reported.

Category

Behavior

2

Description

Intervention 2: first initial questionnaire is completed by the researcher. In intervention group 2, the booklet

contains all the study material provided to the intervention group 1 will be distributed by the patient. Immediately to 1 month postpartum, patients will be followed up by the researcher by telephone and record sheet which includes pregnancy outcomes associated with maternal hospitalizations or hospitalization due to maternal gestational diabetes, the number of hospitalizations, number of days of hospitalization, type of delivery, pregnancy-related outcomes such as infant birth weight, gestational age at birth, the first and fifth Apgar score will be complete. Also stillbirth cases will be reported.

Category
Behavior

3

Description

Control group: first initial questionnaire is completed by the researcher. Patients in the control group would receive routine care hospital. Immediately to 1 month postpartum, patients will be followed up by the researcher by telephone and record sheet which includes pregnancy outcomes associated with maternal hospitalizations or hospitalization due to maternal gestational diabetes, the number of hospitalizations, number of days of hospitalization, type of delivery, pregnancy-related outcomes such as infant birth weight, gestational age at birth, the first and fifth Apgar score will be complete. Also stillbirth cases will be reported.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid akbar abadi hospital
Full name of responsible person
Street address
Molavi Square
City
Tehran

2

Recruitment center

Name of recruitment center
Arash hospital
Full name of responsible person
Street address
Tehranpars
City
Tehran

3

Recruitment center

Name of recruitment center
Jame Zanan hospital
Full name of responsible person

Street address

7th Tir Sq

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Tehran University of Medical Sciences

Full name of responsible person

Doctor Akbar Fotoohi- Deputy Director of Research

Street address

Sixth floor, University of Medical Sciences, Central Building, Ghode street, Keshavarz boulevard-Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Council of Tehran University of Medical Sciences

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

School of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Fateme Rahimikian

Position

Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Master of Midwifery

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Person responsible for updating data

Contact

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Masoomeh Senobari

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Student of master of midwifery

Other areas of specialty/work

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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