

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Investigating the Effect of the Family Physician Referral System on the Rate of Natural Delivery and Pregnancy Outcome and Satisfaction in Pregnant Women Referring to Comprehensive Health Service Centers: Randomized Controlled Trial

Protocol summary

Study aim

Determining the effect of the family physician referral system on the rate of natural delivery and pregnancy outcomes and satisfaction of pregnant women referring to comprehensive health service centers.

Design

The current study is a randomized controlled trial. 188 pregnant women in the first trimester of pregnancy were randomly selected from the health centers of and randomly assigned to two intervention and comparison groups.

Settings and conduct

The health centers of Astana Ashrafiyeh city

Participants/Inclusion and exclusion criteria

pregnant women with their first pregnancy, in the first trimester of pregnancy (between 6 and 12 weeks of pregnancy), who have a normal and low-risk pregnancy (Without obstetric and medical complications based on medical and obstetric history, with desired pregnancy) and no known mental illness, and willing to participate in the study until the end of pregnancy.

Intervention groups

Intervention group: Visits are made by midwives according to the instructions of the national pregnancy care program, except for special care cases, once in every first and second trimester, and three times in the third trimester (32-36-40 weeks). The family doctor will refer the woman. In addition, during pregnancy, childbirth preparation classes will be conducted exactly according to the educational protocol of pregnancy classes. When the labor pains start, the pregnant mother goes to the government hospital and gives birth with physiological birth techniques and labor analgesia. If there is any disturbance in the birth process, the cesarean section will be performed by the same gynecologist. And postpartum care will be done by

comprehensive health service centers up to two months after delivery, as well as a referral to a gynecologist.
control group: care will be carried out according to the normal procedure.

Main outcome variables

Type of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230711058749N1**

Registration date: **2023-07-18, 1402/04/27**

Registration timing: **prospective**

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

Registration date

2023-07-18, 1402/04/27

Registrant information

Name

zahra hamidi madani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3334 6489

Email address

zahra_hamidi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01
Expected recruitment end date
 2026-02-20, 1404/12/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Investigating the Effect of the Family Physician Referral System on the Rate of Natural Delivery and Pregnancy Outcome and Satisfaction in Pregnant Women Referring to Comprehensive Health Service Centers: Randomized Controlled Trial

Public title
 The Effect of the Family Physician Referral System on the rate of Natural Delivery and Pregnancy Outcome and Satisfaction in Pregnant Women Referring to Comprehensive Health Service Centers

Purpose
 Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
 Pregnant women with their first pregnancy (with no history of childbirth or abortion) In the first trimester of pregnancy (between 6 and 12 weeks of pregnancy) Who has a normal and low-risk pregnancy (Without obstetric and medical complications based on medical and obstetric history, with desired pregnancy) No known mental illness Willing to participate in the study until the end of pregnancy.
Exclusion criteria:
 Unwillingness to participate in the study Not attending the training classes during the study

Age
 From **9 years** old to **55 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **188**

Randomization (investigator's opinion)
 Randomized

Randomization description
 For randomization, the method of random blocks will be used with a sequence of 4 and a ratio of 1:1

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

Research Ethics Committees of Guilan university of medical sciences

Street address

Guilan University of Medical Sciences' Headquarters - Parastar St. - Rasht

City

Rasht

Province

Guilan

Postal code

4193713111

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.GUMS.REC.1402.125

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

(O00-O99)

ICD-10 code description

Pregnancy, childbirth and the puerperium

2

Description of health condition studied

Maternal care

ICD-10 code

O30-O48

ICD-10 code description

Maternal care related to the fetus and amniotic cavity and possible delivery problems

3

Description of health condition studied

Complications of labour and delivery

ICD-10 code

O60-O75

ICD-10 code description

Complications of labour and delivery

Primary outcomes

1

Description

Type of delivery

Timepoint

Immediately after delivery

Method of measurement

Observation

Secondary outcomes**1****Description**

Complications of pregnancy

Timepoint

Immediately after delivery

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group:

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Comprehensive health service centers and Kausar Hospital

Full name of responsible person

Zahra Hamidi Madani

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Astana Ashrafieh - Shahid Motahari Boulevard - Shahid Nawab Safavi Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Naghipour

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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

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Zahra Hamidi Madani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Zahra Hamidi Madani

Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments