

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of delivery preparation consult versus routine pregnancy cares on the pregnancy outcome and pregnant women's satisfaction in the Fatemieh Hospital in Hamadan

Protocol summary

Summary

The study aims at determining the effect of delivery preparation consultation on the pregnancy outcome and the pregnant women's satisfaction in the Fatemieh hospital in Hamadan. Pregnancy outcome includes choosing the type of delivery, the experienced delivery, the infant's weight, the weight increase during pregnancy. The inclusion criteria are the pregnant women enjoying complete health, having no specific diseases, not having risky pregnancy, being at the gestational age ranging from 20 to 23 weeks, tending to participate in the educational classes, and not having taken part in similar classes. The population of the study is the pregnant women with mentioned criteria. The size of the sample is 170 women. Eighty five of them, as the experimental group, take part in consultation sessions, and 85 of them, as control group, just receive the routine pregnancy cares. The sampling technique will be randomized permutation block lie, AB BA, where A stands for experimental group and B for the control group. The design of this study is randomized trial-clinical control group. The experimental group will take part in 8 sessions of consultation classes from 20th to 36th week of their, but the control group will be exposed to routine pregnancy cares. Doing so, the pregnancy outcomes and the pregnant women's satisfaction will be compared in the groups. The instruments of collecting data are a researcher-made questionnaire concerning the satisfaction of pregnant women regarding delivery preparation consultation, demographic questionnaire, and the weighing balance of infant's and adult's weight.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012513405N9**

Registration date: **2015-05-19, 1394/02/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-19, 1394/02/29

Registrant information

Name

Seyyedeh Zahra Masoumi

Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0150

Email address

zahra.masoomi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2015-01-30, 1393/11/10

Expected recruitment end date

2015-07-01, 1394/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of delivery preparation consult versus routine

pregnancy cares on the pregnancy outcome and pregnant women's satisfaction in the Fatemieh Hospital in Hamadan

Public title

The effect of delivery preparation consult on the pregnancy outcome and pregnant women's satisfaction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Those women will be included who are certified by the physician to enjoy complete health; not being inflicted with a specific diseases such diabetes, cardio-vascular; their pregnancy will not be of high risk such as multi-twins, repeated abortion, placenta previa, preeclampsia; their gestational age will range from 20 to 23 weeks; having tendency to participate in educational classes; their previous delivery be NVD in the case of multipar women; and have not taken part in the similar educational classes. Exclusion criteria: Those women will be excluded who do not tend to participate in educational classes; make absence more than one session of consult; are not threatened by risk factors such as being conflicted with preeclampsia, amniotic fluid tear and preterm delivery.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 170

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**

Ethics committee of Hamadan University of Medical Sciences

Street address

Research and Technology Deputy, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

6516645977

Approval date

2015-03-02, 1393/12/11

Ethics committee reference number

6371/9/35/16/پ

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

Pregnancy

ICD-10 code

Z34.8

ICD-10 code description

Supervision of other normal pregnancy

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

Birth weight

Timepoint

Immediately after delivery

Method of measurement

Weighing balance of infant's weight

2**Description**

Choosing the type of delivery

Timepoint

20th and 36th week of pregnancy

Method of measurement

Questionnaire

3**Description**

The type of delivery

Timepoint

Immediately after delivery

Method of measurement

Questionnaire

4**Description**

Satisfaction

Timepoint

Before the intervention, after finishing the consult sessions

Method of measurement

Questionnaire

5**Description**

The weight increase of mother during pregnancy

Timepoint

20th and 36th week of pregnancy

Method of measurement

Weighing balance

Secondary outcomes

1

Description

Apgar score

Timepoint

Immediately after delivery

Method of measurement

Check list

Intervention groups

1

Description

Experimental group: holding 8 session of consulting for pregnant women included nutrition, exercise, description about normal vaginal delivery etc, each taking 90 minutes

Category

Prevention

2

Description

Control group: routine pregnancy cares for pregnant women

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Simin Karimi (M.sc student of Consulting in Midwifery)

Street address

Fatemieh Hospital, Hamadan

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Said Bashirian, Ph.D

Street address

Research and Technology Deputy, Hamadan
University of Medical Sciences, Hamadan, Iran

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan 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

Hamadan University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Masoumi

Position

Associate professor

Other areas of specialty/work

Street address

The Faculty of Nursing and Midwifery, Hamadan
University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

6516845977

Phone

+98 81 3838 0150

Fax

+98 81 3838 0447

Email

zahramid@yahoo.com; zahra.masoomi@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Seyedeh Zahra Masoumi

Position

Associate professor

Other areas of specialty/work

Street address

The Faculty of Nursing and Midwifery, Hamadan
University of Medical Sciences, Hamadan, Iran

City
Hamadan
Postal code
6516645977
Phone
+98 81 3838 0150
Fax
+98 81 3838 0447
Email
zahramid@yahoo.com; zahra.masoomi@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Simin Karimi
Position
M.sc student of Consulting in Midwifery
Other areas of specialty/work
Street address
The Faculty of Nursing and Midwifery, Hamadan
University of Medical Sciences, Hamadan, Iran
City

Hamadan
Postal code
6515917734
Phone
+98 81 3824 5111
Fax
Email
Karimi.midwife.65@Gmail.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