

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of effect of self-care education on pregnancy outcome in women with preeclampsia: A randomized clinical trial

Protocol summary

Summary

The aim of this study is effect of self care education on pregnancy outcome in women with preeclampsia. After explaining the purpose of the study and obtaining the informed consent, patients will be randomly allocated into A and B groups. Randomization will be performed using random block sizes of 4. The study is randomized, free placebo. Inclusion criteria: Pregnant women with gestational age more than 20 weeks with gestational hypertension. Exclusion criteria: Twin pregnancy, history of intrauterine growth restriction, congenital malformation, chronic diseases(diabetes, hypertension, cardiovascular, renal, hematologic, thyroid). Sample size: 60 patients are participated in the study with 30 patients in each group. The intervention used in the study: Self care education for 30 minutes to 4 times. Primary outcome: Maternal outcomes in pregnancy period, during and after delivery. Secondary outcome: Neonatal outcomes in pregnancy period, during and after delivery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061128385N1**

Registration date: **2016-10-07, 1395/07/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-10-07, 1395/07/16

Registrant information

Name

Zahra Shams

Name of organization / entity

Shahrood Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 11 3536 4011

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Islamic Azad University of Shahrood

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effect of self-care education on pregnancy outcome in women with preeclampsia: A randomized clinical trial

Public title

The effect of self-care education on pregnancy outcome in women with preeclampsia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with gestational age more than 20 weeks with gestational hypertension

Exclusion criteria: Twin pregnancy; history of intrauterine growth restriction; congenital malformation; diabetes; hypertension; cardiovascular disease, renal disease, hematologic disease, thyroid disease)

Age

No age limit
Gender
Female
Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: 60
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 Shahrood University of Medical Sciences

Street address

Shahrood University of Medical Sciences, Haft Tir Square, Shahrood

City

Shahrood

Postal code

3613773955

Approval date

2015-08-26, 1394/06/04

Ethics committee reference number

IR.SHMU.REC.1394.78

Health conditions studied

1

Description of health condition studied

Pre eclampsia

ICD-10 code

O14.9

ICD-10 code description

Pre-eclampsia, unspecified

Primary outcomes

1

Description

Maternal outcomes
Timepoint
During pregnancy and during and after delivery
Method of measurement
Questionnaire

Secondary outcomes

1

Description

Neonatal outcomes

Timepoint

During pregnancy and during and after delivery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Self care education for 4 sessions and each session is 30 minutes

Category

Lifestyle

2

Description

Control group: Non use of self care education

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein education, Research and Treatment Center, Shahrood

Full name of responsible person

Dr Mohammad Esmaeil Ajami

Street address

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Islamic Azad University of Shahrood

Full name of responsible person

Dr Sahebali Manafi

Street address

Shahrood Islamic Azad University, Tehran Blvd, Shahrood

City
Shahroud

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for Research and Technology, Islamic Azad University of Shahrood

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
Islamic Azad University of Shahrood

Full name of responsible person
Zahra Shams

Position
Medical Student

Other areas of specialty/work

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Person responsible for updating data

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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