

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Application of Orem self-care model for the management of pre-eclampsia in pregnant women and their fetus' health

Protocol summary

Summary

Pre-eclampsia is a multi-system disorder that clinically by hypertension and proteinuria, with or without symptoms, laboratory results deteriorate, after 20 weeks of gestation. The aim of this study is to effect of Orem self-care model application in management of pre-eclampsia in pregnant women and their fetus' health. The semi-experimental study will carry out on 60 women with preeclampsia in referents to Fatemeh hospital in Hamadan city, Iran. Written informed consent will obtain from all participants. The participants will randomly select to one of two educations (case) and without education (control) groups. Interventions include: understanding the patient about pre-eclampsia, complications of disease, risk factors and the need to avoid them, the use of prescribed medications and regular visits to the doctor. Intervening period is one month. Women and their fetus' health before and after the one month intervention of Orem self-care model will compare with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107216888N2**

Registration date: **2013-12-20, 1392/09/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

Name

Fatemeh Shobeiri

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 6051

Email address

shobeiri@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology Faculty of Medical Sciences (School of Nursing and Midwifery)

Expected recruitment start date

2013-09-27, 1392/07/05

Expected recruitment end date

2014-02-19, 1392/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Application of Orem self-care model for the management of pre-eclampsia in pregnant women and their fetus' health

Public title

Effect of Application of Orem self-care model for the management of pre-eclampsia in pregnant women and their fetus' health Fatemeh hospital

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of physician diagnosis of pre-eclampsia ; A lack of underlying cardiovascular disease; Singleton fetus ; Living in Hamadan order to attend; Gestational age over 20 weeks; a primary and higher education; Lack of mental illness. Exclusion criteria: <15

age >45: Diabetes.

Age
From **15 years** old to **45 years** old

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

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Postal code

65178

Approval date

2013-07-24, 1392/05/02

Ethics committee reference number

16/35/9/1344

Health conditions studied

1

Description of health condition studied

Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium

ICD-10 code

010-016

ICD-10 code description

Oedema, proteinuria and hypertensive disorders in pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Infant health

Timepoint

After one month intervention

Method of measurement

Questionnaire

2

Description

pre-eclampsia management

Timepoint

After one month intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Three sessions of Orem self-care model education in management of pre-eclampsia, intervention concepts related to hypertension, proteinuria, various aspects of lifestyle and diet will be conducted

Category

Other

2

Description

Control group: With out any intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Fatemeh Shobeiri

Street address

Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan, Iran

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Fahmiheh Street, Hamadan University of Medical Sciences, Department of Research and Technology

Full name of responsible person

Heidar Tavalani

Street address

No. 307, Fahmideh Street, Hamadan University of Medical sciences Hamadan

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fahmiheh Street, Hamadan University of Medical Sciences, Department of Research and Technology

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

Fatemeh Shobeiri

Position

Ph.D. in Maternal and Child Health

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