

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Clinical trial to compare random urine protein-creatinine ratio and protein dip stick with 24-hour urine protein to diagnosis preeclampsia in pregnant women that are

Protocol summary

Summary

In this study, three methods of laboratory diagnosis of preeclampsia include 24-hour urine protein measurement, random urine protein-creatinine ratio and protein dip stick, to be compared. Gold standard diagnosis of preeclampsia is the 24-hour urine protein measurement. Since the collection of the 24h urine sample is a mundane procedure, for both the patient and the hospital staff, furthermore it is not always collected properly, it may lead to incorrect protein reports. Therefore various studies have been conducted on methods of diagnosing preeclampsia such as random urine protein-creatinine ratio and protein measurement with dip stick. In this study those women who's gestational age exceeds 20 weeks, and are suspicious of preeclampsia are included. Diagnosis of mild or severe preeclampsia is based on blood pressure and other diagnostic criteria. Those who had chronic diseases which lead to primary proteinuria and those who did not collect their 24-hour urine sample correctly will be excluded from the study. In this study, 86 patients participate. On urine specimens of each patient every three diagnostic methods are performed. This study doesn't have control group. When the patients hand in their 24-hour urine sample, a random urine sample will be collected in which the protein-creatinine ratio and the dip stick protein is measured. Intervention is done in this study, is doing two new diagnostic tests on patients random urine sample. Variables in this study are random urine protein and creatinine and dip stick protein.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102125810N1**
Registration date: **2011-02-25, 1389/12/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-25, 1389/12/06

Registrant information

Name

Nazanin Atrvash

Name of organization / entity

Hamedan university of Medical science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamedan University of Medical Sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare random urine protein-creatinine ratio and protein dip stick with 24-hour urine protein to

diagnosis preeclampsia in pregnant women that are

Public title

Comparison of three methods of pregnancy poisoning diagnosis

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: " Pregnant women with gestational age higher than 20 weeks that are suspicious of preeclampsia ". Exclusion criteria: Since there are lots of factors which lead to proteinuria, below patients will be discluded from the study: 1. " Patients with secondary glomerulonephropathy " a: " Diabetes mellitus " b: "Lupus " c: " Active infectious like Hepatitis B and C , Syphlis , Malaria , Endocarditis , HIV " d: " Long and digestive cancer , Lymphoma " 2. " Drug induced glomerulonephropathy " a: " Heroin " b: " NSAID usage " c: " Lithium " 3. " Tubular reasons " a: " Chronic Hypertension " " And of those patients who did not collect their 24-hour urine sample accordingly ". (based on 24-hour urine creatinine)

Age

From **15 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

ثبت نشده است

Secondary trial Id

ثبت نشده است

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences and Health Services, Kashani st beggining, Khaje Rashid conjunction, Hamedan

City

Hamedan

Postal code

Approval date

2011-02-14, 1389/11/25

Ethics committee reference number

16/35/9/176707/پ

Health conditions studied

1

Description of health condition studied

Preeclampsia

ICD-10 code

O10, O11,

ICD-10 code description

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

Primary outcomes

1

Description

Blood Pressure

Timepoint

Blood pressure is measured once when the patient is visited for the first time and every 6 hours when the patient is hospitalized. Protein and creatinine are measured once in a 24-hour urine sample and once in a random urine sample. Protein is also measured using the dip stick in a random urine.

Method of measurement

Blood pressure measured with mercury barometer based on " mmHg " .

2

Description

Creatinine

Timepoint

Creatinine is measured once in 24-hour urine sample and random urine sample when the samples was given.

Method of measurement

Creatinine is measured with special laboratory kit and it's based on " mg/dl " .

3

Description

Protein

Timepoint

Protein is measured once in 24-hour urine and random urine samples when the samples were given.

Method of measurement

Protein is measured with special laboratory kit. Its scale in 24-hour urine sample is " mg/24h " and in random urine sample is " mg " .

Secondary outcomes

1

Description

Liver enzymes (AST-ALT-Bil)

Timepoint

They're measured once.

Method of measurement

They're measured with special laboratory kit.

2

Description

Platelets

Timepoint

It's measured once.

Method of measurement

It's measured with special laboratory kit.

Intervention groups

1

Description

In this study, 24-hour urine protein is measured once with special laboratory kit on all patients samples

Category

Diagnosis

2

Description

In this study, a random urine sample is taken from the patients, in which the amount of protein and creatinine with special laboratory kit is measured.

Category

Diagnosis

3

Description

On patients random urine samples an amount of dip stick protein is measured.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Fatemieh Obstetrics and Gynecology Hospital

Full name of responsible person

Mr. Zolfaghari

Street address

Fatemieh Obstetrics and Gynecology Hospital,
Kermanshah st, Shariati square, Hamedan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamedan University of Medical Sciences and Health Services

Full name of responsible person

Ms. Ahmadkhani

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Hamedan University of Medical Sciences and Health Services, Kashani st beggining, Khaje Rashid conjunction, Hamedan

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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

Vice chancellor for research, Hamedan University of Medical Sciences and Health Services

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

Hamedan university of Medical Science and Health Service

Full name of responsible person

Nazanin Atrvash

Position

Medical student

Other areas of specialty/work

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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