

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 whose 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3821 3994

###### Email address

n.atrvash@umsha.ac.ir

##### 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

Hamedan

## 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

##### Street address

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

#### City

Hamedan

#### 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

##### Street address

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#### Postal code

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

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Service

**Full name of responsible person**

Dr. Shahla Nasrolahi

**Position**

Associate Professor of Obstetrics and Gynecology  
Surgery

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**Full name of responsible person**

Nazanin Atrvash

**Position**

Medical student

**Other areas of specialty/work****Street address**

#40, West Emdad st, North Sheikhbayi st, Molasadra  
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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*