Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 mondaine 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

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Nazanin Atrvash

Name of organization / entity

Hamedan university of Medical science

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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 poisining 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, 011,
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. It 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
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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
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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