Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Pap smear quality with spatula-cytobrush versus cervix brush methods in women 21-65 years old

Protocol summary

Summary

Main outcomes: Using the best device for Pap smear Design: This study designed as a randomized clinical trial study, not blinded, crossover. Setting and conduct: All married women between 21-65 years old who have indication for pap smear included in study and in first time will be collected sample for pap smear with one of cervix brush or cytobrush-spatula and 30 days later test will repeated with the other device then samples will be send for reporting to a pathologist who has not any information about patients and Pap smear devices. Then results analyzed and described by BETHESDA system. Participants inclusion and exclusion criteria: In both time patient with clinical infection or PID or vaginal discharge or intercourse for 48 h ago or administer vaginal agent or pregnant person will be deleted as person that in first result of Pap smear have infection. Intervention: Dose not has. Objectives measures variables: pap smear

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111811504N1**
Registration date: **2013-08-11, 1392/05/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-08-11, 1392/05/20

Registrant information

Name
Sanam Moradan
Name of organization / entity
Semnan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Semnan University of Medical Science

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-10-23, 1392/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pap smear quality with spatula-cytobrush versus cervix brush methods in women 21-65 years old

Public title

Comparison of Pap smear quality with spatula-cytobrush versus cervix brush methods

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: married women between 21-61 years old who have indication for pap smear. Exclusion criteria: Clinical infection or PID; vaginal bleeding ; intercourse in 48 h ago; use of vaginal agent; pregnancy; person who had infection in first pap smear; person who dosent come for second time.

Age

From **21 years** old to **65 years** old

Gender

Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **260**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Semnan University of Medical Sicense
Street address
Central Department, Semnan University of Medical Sicense, Basidj Bulvard
City
Semnan
Postal code
Approval date
2012-11-13, 1391/08/23
Ethics committee reference number
91/16/10616

Health conditions studied

1

Description of health condition studied
Comparison of Pap smear quality in two methods
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
adequacy of cell
Timepoint
1 mounts after intervention
Method of measurement
result of the papsmear

Secondary outcomes

1

Description
sub clinical infection
Timepoint
1 mount after intervention
Method of measurement
result of the papsmear

Intervention groups

1

Description
All patients who have enclosion criteria undergo pop smear and in first time with one of cervix brush or cytobrush_spatula then samples send to laboratory and blindly describe them with BETHESDA
Category
Diagnosis

2

Description
30 days after first examination the test repeated with the other device and samples send to laboratory for description.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al Momenin Hospital
Full name of responsible person
Sanam Moradan
Street address
Amir Al Momenin Hospital, Imam Hussein Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Semnan University of Medical Science
Full name of responsible person
Raheb Ghorbani
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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 of Semnan University of Medical Science
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
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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