

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The comparison of Pap smear quality between the method of Anatomical spatula and common method (spatula-cytobrush) in women referred to gynecology clinics

Protocol summary

Summary

Objectives: The aim of this study was to evaluate the quality of sampling with Anatomical spatula compared with spatula-cyto brush. Patients included 200 women who were married and referred to gynecology clinic. **Inclusion criteria:** married, not pregnant, not using vaginal cream. **Exclusion criteria:** Severe cervicitis, severe genital infection, cuitus in two days before sampling. **Intervention:** after the interview and filling out the form of Pap smear, first sampling was done with spatula-cytobrush and then anatomical spatula. All slides encoded by two pathologists assigned. **Primary outcome:** quality of sampling with two different spatulas.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009121548N11**

Registration date: **2011-01-16, 1389/10/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-01-16, 1389/10/26

Registrant information

Name

Khadijeh Abdali

Name of organization / entity

Fatemeh college of nursing and midwifery, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4255

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abdalikh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2010-01-10, 1388/10/20

Expected recruitment end date

2010-05-02, 1389/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Pap smear quality between the method of Anatomical spatula and common method (spatula-cytobrush) in women referred to gynecology clinics

Public title

The comparison of Pap smear quality with two different methods

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: married, not pregnant, not using vaginal cream. Exclusion criteria: Severe cervicitis, severe genital infection, cuitus in two days before sampling.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 200

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Postal code

Approval date

2009-09-13, 1388/06/22

Ethics committee reference number

88/4702

Health conditions studied

1

Description of health condition studied

Pap smear

ICD-10 code

Z00

ICD-10 code description

General examination and investigation of persons without complaint and reported diagnosis

Primary outcomes

1

Description

the present of adequacy of cells and endocervical cells

Timepoint

after sampling

Method of measurement

two pathologist report

Secondary outcomes

1

Description

Distribution of cellular infection and inflammations

Timepoint

after sampling

Method of measurement

two pathologists report

Intervention groups

1

Description

Pap smear with Anatomical spatula

Category

Prevention

2

Description

Pap smear with spatula-cytobrush

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeinabieh hospital and gynecology clinics of Shiraz University of Medical Sciences

Full name of responsible person

Khadijeh Abdali

Street address

Fateme Zahra nursing and midwifery faculty, Namazi squer

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr Mohammad Hossein Dabbaghmanesh

Street address

Namazi squer

City

Shiraz

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, Shiraz University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Vijinda Komar

Position

Professor

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