

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of cervical cleaning with a big cotton swab on pap smear samples quality

Protocol summary

Summary

Objective: Cervical cancer is one of the most frequent female cancers which is usually diagnosed late. Papanicolaou test is an important screening tool for its early diagnosis, but it has too many false-negative results. We evaluated in this study the effect of cervical discharge cleaning with a big cotton swab before taking the smear on increase diagnostic efficacy of this test. Materials and methods: This study is a randomized clinical trial which was conducted from September 2007 until December 2010 in 500 women who came to Tehran Bouali Hospital gynecology clinic and had indication for papanicolaou test. These women were divided into two groups as case and control by random allocation. In case group before taking the smear, cervical discharge was cleaned by a big cotton swab. In control group the smear was taken in traditional way with spatula. At last the quantity (presence of 8000-12000 squamous cells), quality (presence or absence of endocervical cells) and amount of inflammatory exudates in the smears (high: coverage of >75% of smear, moderate: coverage of 50-75% of smear, low: coverage of <50% of smear with inflammatory exudate) were compared in two groups using Mann-witney, χ^2 , Fisher-exact test and t-student test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112318560N1**
Registration date: **2012-04-08, 1391/01/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-04-08, 1391/01/20

Registrant information

Name

Gita Hatamizadeh

Name of organization / entity

Tehran Medical Branch of Islamic Azad University

Country

Iran (Islamic Republic of)

Phone

+98 21 2231 1587

Email address

ghatamizadeh@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2007-09-23, 1386/07/01

Expected recruitment end date

2010-12-20, 1389/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cervical cleaning with a big cotton swab on pap smear samples quality

Public title

The effect of cervical cleaning with a big cotton swab on pap smear samples quality

Purpose

Screening

Inclusion/Exclusion criteria

Inclusion criteria: all women with history of coitus; women who had not pap smear from one year ago.

Exclusion criteria: acute vaginitis or cervicitis; vaginal bleeding; a history of total hysterectomy; menopause

women; pregnant women.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **500**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran medical branch of Islamic Azad university

Street address
Zargandeh st., Shariati Ave.

City
Tehran

Postal code
1495/19395

Approval date
2006-12-04, 1385/09/13

Ethics committee reference number
4396

Health conditions studied

1

Description of health condition studied
cervical carcinoma

ICD-10 code
C53

ICD-10 code description
Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

quantity (presence of 8000-12000 squamous cells)

Timepoint
sampling is done at the same time when cervix is cleaned

Method of measurement
Bethesda criteria

2

Description
quality (presence or absence of endocervical cells)

Timepoint
sampling is done at the same time when cervix is cleaned

Method of measurement
Bethesda criteria

3

Description
amount of inflammatory exudates in the smears (high: coverage of >75% of smear, moderate: coverage of 50-75% of smear, low: coverage of <50% of smear with inflammatory exudate)

Timepoint
sampling is done at the same time when cervix is cleaned

Method of measurement
Bethesda criteria

Secondary outcomes

empty

Intervention groups

1

Description
cleaning of cervical discharge by a big cotton swab before taking sample for pap smear

Category
Early detection

2

Description
no intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Booali hospital gynecology clinic

Full name of responsible person
Dr. Gita Hatamizadeh

Street address
Emam Hosein square, Damavand ave.

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gita Hatamizadeh

Full name of responsible person

Gita Hatamizadeh

Street address

Emam Hosein square- Damavand ave.

City

Tehran

Grant name

بودجه توسط محقق فراهم شده است

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gita Hatamizadeh

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Tehran medical branch of Islamic Azad university

Full name of responsible person

Gita Hatamizadeh

Street address

Zargandeh street, Shariati ave.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran medical branch of Islamic Azad university

Proportion provided by this source

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

Dr. Gita Hatamizadeh

Full name of responsible person

Dr. Gita Hatamizadeh

Position

OB-GYN/ Infertilityfellowship

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr.Gita Hatamizadeh

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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