

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of Papsmear adequacy with either Ayrespatula and Cervix brush in patients referred to a private medical office, 2007-2008

Protocol summary

Summary

The aim of this study is comparison of Pap smear adequacy by two instrument Ayre spatula and cervix brush in patient who referred to a private clinic. This study is a clinical trial 400 patient who needs to perform Pap smear randomized in two groups with block randomized half by Ayre spatula and half by cervix brush. Inclusion criteria include all patients who need to perform Pap smear. Exclusion criteria include: pregnant women, women who is on HRT and the patients with cervicitis. The specimen were evaluated (by one pathologist) based on Bethesda classification. The primary result was existence or absence of endocervical cell and classified into two groups. Adequate or inadequate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206131306N4**

Registration date: **2012-07-10, 1391/04/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-10, 1391/04/20

Registrant information

Name

Ziba Zahiri

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

drzibazahiri@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research – Guilan university of medical sciences

Expected recruitment start date

2007-07-09, 1386/04/18

Expected recruitment end date

2009-08-17, 1388/05/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Papsmear adequacy with either Ayrespatula and Cervix brush in patients referred to a private medical office, 2007-2008

Public title

Comparison of Papsmear adequacy with either Ayrespatula and Cervix brush

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criterion: all patients who need to perform Pap smear. Exclusion criteria: pregnant women who are under HRT and the patients with cervicitis.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 198

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

medical school, Guilan university of Medical sciences

Street address

Tehran street

City

Rasht

Postal code

Approval date

2007-07-09, 1386/04/18

Ethics committee reference number

1233

Health conditions studied

1

Description of health condition studied

Comparison of Papsmear adequacy with either Ayrespatula and Cervix brush

ICD-10 code

U00-U49

ICD-10 code description

Provisional assignment of new diseases of uncertain etiology

Primary outcomes

1

Description

Adequacy of pap smear in Ayre spatula and Cervix brush

Timepoint

Between menstrual cycle

Method of measurement

with Ayre spatula and Cervix brush

Secondary outcomes

1

Description

Adequacy of pap smear in Ayre spatula and Cervix brush by parity

Timepoint

Between menstrual cycle

Method of measurement

with Ayre spatula and Cervix brush

2

Description

Adequacy of pap smear in Ayre spatula and Cervix brush by Menopause

Timepoint

one year after Lack of menstruation

Method of measurement

with Ayre spatula and Cervix brush

3

Description

adequacy of Causes of non-satisfactory in Ayre spatula and Cervix brush

Timepoint

Between menstrual cycle

Method of measurement

Based on presence or absence of an adequate endocervical cells

Intervention groups

1

Description

use Ayre spatula in first group

Category

Diagnosis

2

Description

use Cervix Brush in second group

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Private practice

Full name of responsible person

Dr Ziba Zahiri

Street address

Reproductive health research Center, Al_Zahra Hospital, Namjoo Street

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research – Guilan university of medical sciences

Full name of responsible person

Dr Abdol Rasol Sobhani

Street address

Guilan University Of Medical Sciences

City

Rasht

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 – Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Dr Ziba Zahiri

Position

Associated professor Gilan University of Medical Science

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

seyedeh maryam mosavi chahardeh

Position

B.S. midwife

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