Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of lubricant gel on the satisfactory results of liquid-based Pap smear

Protocol summary

Study aim
Does the usage of lubricant gel change the result of satisfactory in liquid-based Pap Smear?

Design
Randomize clinical trial with a parallel control group,one blinded,on 253 patient in each group that randomize with random number table.

Settings and conduct
In this study patients who come to Shariati hospital,gynecologic office is checked for indication of cervical cancer screening and pap smear,if it's positive after their informed consent they will be in intervention group or control with online randomize number table. Liquid-based pap smear will done for them by use of lubricant gel or water,then the specimen will study with pathologist.Patients and pathologist won't know whether the lubricant is used or not.

Participants/Inclusion and exclusion criteria
They are women more than 21 year old who candidate for cervical cancer screening;and if they don't accept to be in the study or if they have congenital uterine,cervical,vaginal anomaly or cervical cancer exclude from the study

Intervention groups
In intervention group after speculum lubricate with lubricant gel pap smear is done ,but in control group only water is used for this pupose.

Main outcome variables
satisfactory of sample

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160615028486N2**
Registration date: **2022-03-02, 1400/12/11**
Registration timing: **registered_while_recruiting**
Last update: **2022-03-02, 1400/12/11**
Update count: **0**

Registration date
2022-03-02, 1400/12/11

Registrant information

Name
Mansooreh Yaraghi

Name of organization / entity
Tehran University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-01, 1400/11/12

Expected recruitment end date
2022-05-01, 1401/02/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of lubricant gel on the satisfactory results of liquid-based Pap smear

Public title
Effect of lubricant gel on the satisfactory results of liquid-based Pap smear

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
Screening for cervical cancer
Exclusion criteria:
History of cervical cancer History of uterine,cervical,vaginal congenital anomaly Patient disagreement

Age
From **21 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **506**

Randomization (investigator's opinion)
Randomized

Randomization description
we search online randomize number in googl.com ,then we choose 253 number from 506 in kitset.ir/numbers/random .

Blinding (investigator's opinion)
Single blinded

Blinding description
Pap smear test is performed during gynecologic exam.The person who does it based on patient's number uses lubricant gel or not.The samples are sent to pathological laboratory and with other samples which aren't in the study and/or from other centers will be assessed by pathologists.They don't know if lubricant gel is used or not.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
506,6th foor,Centar building of Tehran University of Medical ScienceUniversity,Ghods Street,Keshavarz Street

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2021-03-16, 1399/12/26

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.1308

Health conditions studied

1

Description of health condition studied
screening for malignant neoplasm of cervix

ICD-10 code
Z12.4

ICD-10 code description
Encounter for screening for malignant neoplasm of cervix

Primary outcomes

1

Description
Satisfactory result of Pap Smear in both group

Timepoint
When Pap Smear result is ready

Method of measurement
Pathologist reports for at least 5000 squamous cell in bottle

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: usage of lubricant gel ,Palizteb factory,water soluble ,with Carbomers ,on speculum during pap smear test.

Category
Diagnosis

2

Description
Control group:use of water on speculum during pap smear test.

Category
Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital Gynecology Clinic

Full name of responsible person
Mansooreh Yaraghi

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Jalal Al-Ahmad,North Kargar

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mansooreh Yaraghi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Demographic characteristic of patient,last coitus,last menstrual period,study result

When the data will become available and for how long
Three mounts after publication of result

To whom data/document is available
All people who work in this field

Under which criteria data/document could be used
every time

From where data/document is obtainable
Mansooreh Yaraghi dr_m_yaraghi@yahoo.com

What processes are involved for a request to access data/document
Send an e-mail to Mansooreh Yaraghi

Comments