

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8828 0618

###### Email address

dr\_m\_yaraghi@yahoo.com

##### 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 floor,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

**Street address**

Jalal Al-Ahmad,North Kargar

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
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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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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 months 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**