

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of cervical specimen margins obtained from LEEP surgery with and without colposcop

Protocol summary

Study aim

Comparison of cervical specimen margins obtained from LEEP surgery with and without colposcopy

Design

The clinical trial has an intervention control group, with parallel groups, single blind and completely randomized. This study is performed on 140 patients. Rand function is done in Excel software for randomization.

Settings and conduct

All patients referred to the clinic of Mahdiah and Imam Hossein hospitals who become LEEP candidates for any reason are divided into two groups after obtaining consent. In one group, a colposcope is used during LEEP, and in the other group, without a colposcope and only after acetic acid is applied to the cervix and observed with a flat eye (VIA), LEEP is performed on patients who have been blinded. , Are entered completely randomly in each group and the LEEP operation is performed by two gynecological oncology fellowships and the samples are examined by an experienced pathologist.

Participants/Inclusion and exclusion criteria

Entry requirements: All patients referred to the clinic of Mahdiah and Imam Hossein hospitals That become LEEP candidates for any reason. No entry conditions: Patients who do not consent to participate in the project Patients undergoing LEEP for the second time.

Intervention groups

All patients referred to the oncology clinic who have undergone colposcopy for any reason and are candidates for LEEP with pathological results based on CIN2 and CIN3 are admitted to the study after obtaining consent and are divided into two groups in a LEEP surgery group with colposcopy. It is performed during the operation and in the other group, the LEEP operation is performed by VIA method and the two groups are examined in terms of the sample size and the margin of the removed tissue.

Main outcome variables

Sample size and number of parts and margin of LEEP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201121049454N1**

Registration date: **2021-10-21, 1400/07/29**

Registration timing: **prospective**

Last update: **2021-10-21, 1400/07/29**

Update count: **0**

Registration date

2021-10-21, 1400/07/29

Registrant information

Name

Atefeh Moridi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 2628

Email address

a.moridi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cervical specimen margins obtained from LEEP surgery with and without colposcop Public title Comparison of cervical specimen margins obtained from LEEP surgery with and without colposcop Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: All patients between the ages of 15 and 49 years referred to Mahdiah and Imam Hossein Hospitals who become LEEP candidates for any reason Exclusion criteria: Patients who do not consent to participate in the project Patients undergoing LEEP for the second time Patients under 15 years and over 49 years of age. Age From 15 years old to 49 years old Gender Female Phase N/A Groups that have been masked Participant Sample size Target sample size: 140 More than 1 sample in each individual Number of samples in each individual: 1 A patient who is candidate for LEEP and has her informed consent taken Randomization (investigator's opinion) Randomized Randomization description To equalize the two groups, we use the block randomization method. First, we consider the capacity of the block 4 and determine all permutations (6 blocks). All possible blocks are arranged as follows: Block 1: ABAB, Block 2: AABB, Block 3: ABBA, Block 4: BBAA, Block 5: BAAB and Block 6: BABA. We called these blocks randomly from numbers 1 to 6. Choose a random number between 1 and 6. For example, the number 4 was chosen randomly, so the first person receives treatment "B", the second person receives treatment "B", the third person receives treatment "A" and the fourth person receives treatment "A", which indicates the block 4 is the first block for patients entering the study. Then we select the second block at random. This process is repeated until we reach the desired sample. Blinding (investigator's opinion) Single blinded Blinding description The participants are assigned to study A and B codes and until the end of the study, these codes are not decoding for patients. That is, participating people, until the end of the study, are not informed that LEEP surgery with colposcopy is for group A or B groups. Placebo Not used Assignment Parallel	Other design features Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics Committee in Biomedical Research of Shahid Beheshti University of Medical Sciences Street address Iran TV Street City Tehran Province Tehran Postal code ۱۴۱۹۹۴۳۴۷۱ Approval date 2020-10-26, 1399/08/05 Ethics committee reference number IR.SBMU.MSP.REC.1399.377 Health conditions studied <u>1</u> Description of health condition studied cervical cancer ICD-10 code ICD-10 code description Primary outcomes <u>1</u> Description Number of parts and sample size of LEEP Timepoint After surgery with pathology results Method of measurement Number of pieces sent for pathology and length, width and height reported based on pathology answer Secondary outcomes <u>1</u> Description LEEP sample margin Timepoint After surgery with pathology results Method of measurement Negative or positive cases reported in pathology
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Intervention groups

1

Description

Intervention group: All patients referred to the clinic of Mahdiah and Imam Hossein hospitals who are LEEP candidates for any reason are divided into two groups after obtaining consent. In one group, a colposcope is used during the LEEP and the cervix is viewed under armed vision. The LEEP operation is performed and the patients are entered into each group based on a random table. The LEEP operation is performed by two gynecological oncology fellowships. Examined by an experienced pathologist

Category

Treatment - Surgery

2

Description

Control group: Patients referred to the clinic of Mahdiah and Imam Hossein hospitals who are candidates for LEEP for any reason are divided into two groups after obtaining consent. In the control group during LEEP without colposcope and only after applying acetic acid on the cervix and view with the naked eye LEEP operation is performed by two gynecological oncology fellowships. Examined by an experienced pathologist

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr. Farah Farzaneh

Street address

Shahid Madani Street

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1617763141

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Fax

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2

Recruitment center

Name of recruitment center

Mahdiah Hospital

Full name of responsible person

Atefeh Muridi

Street address

Fadaiyan-e-Islam St. - Shishegar Khaneh Alley - Shahid Rajabnia St.

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mahdiah_hospital@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Atefeh Moridi

Street address

Shahid Chamran Highway, Yemen St. - Shahid Arabi St. next to Ayatollah Taleghani Hospital

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1985717443

Phone

+98 21 2243 2040

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atefeh Moridi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Other areas of specialty/work

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Fax**Email**

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

After printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Provided that the complete details of the data are entered.

From where data/document is obtainable

a.moridi@sbmu.ac.ir

What processes are involved for a request to access data/document

Send request via email

Comments