

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Sep 2026

Comparison of lateral thermal damage during colpotomy using harmonic scalpel versus monopolar diathermy in women undergoing laparoscopic hysterectomy

Protocol summary

Study aim

Comparison of lateral thermal damage depth using ultrasonic and monopolar energy during colpotomy in laparoscopic hysterectomy

Design

a double-blind randomized clinical trial

Settings and conduct

Rasoul-e-Akram Hospital

Participants/Inclusion and exclusion criteria

70 women who are candidates for laparoscopic hysterectomy

Intervention groups

The control group includes 35 women in whom monopolar energy is used for colpotomy and the case group includes 35 women in whom harmonic scalpel is used during laparoscopic hysterectomy.

Main outcome variables

The amount of lateral thermal damage in cervical tissues obtained from patients The colpotomy step duration

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6650 9283

Email address

chaichian.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-07, 1397/07/15

Expected recruitment end date

2019-10-07, 1398/07/15

Actual recruitment start date

2018-10-01, 1397/07/09

Actual recruitment end date

2019-03-17, 1397/12/26

Trial completion date

2019-04-27, 1398/02/07

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180130038567N2**

Registration date: **2018-09-30, 1397/07/08**

Registration timing: **prospective**

Last update: **2019-06-10, 1398/03/20**

Update count: **1**

Registration date

2018-09-30, 1397/07/08

Registrant information

Name

shahla chaichian

Scientific title

Comparison of lateral thermal damage during colpotomy using harmonic scalpel versus monopolar diathermy in women undergoing laparoscopic hysterectomy

Public title

Comparison of thermal damage between harmonic and monopolar energy in laparoscopic hysterectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women in age range 18-60 Women diagnosed with benign gynecologic diseases including myoma, adnomyosis ... who are candidates for total laparoscopic hysterectomy Not suffering from background diseases affecting wound healing process including immune

deficiency, long-term use of corticosteroids or history of pelvic irradiation

Exclusion criteria:

Any woman suspicious of cervical or vaginal malignancy
Presence of active vaginal infection during last 30 days
Use of antibiotics other than the preoperative prophylaxis

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **4**

histologic blocks of cervical tissue in four zones :

anterior, posterior, right lateral and left lateral

Actual sample size reached: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 70 women undergoing laparoscopic hysterectomy will be divided into two groups of 35 using simple randomization method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blinding (patients and outcome investigators will not be aware of the allocation and the surgeons will be informed of randomization only on the day of surgery). Since the device is used during surgery when the patient is anesthetized, she will be actually blind to the randomization.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

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Tehran

Province

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Postal code

1449614535

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.IUMS.REC.1397.233

Health conditions studied

1

Description of health condition studied

Benign uterine diseases

ICD-10 code

N71.9

ICD-10 code description

Inflammatory diseases of uterus, unspecified

Primary outcomes

1

Description

measuring the depth of lateral thermal damage developed in cervical tissue

Timepoint

within 72 hours after intervention

Method of measurement

measuring with specific microscope used by pathologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 35 women for whom, ultrasonic device (Harmonic) is used for colpotomy.

Category

Treatment - Surgery

2

Description

Control group: 35 women in whom, monopolar device is used for colpotomy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram hospital

Full name of responsible person

Shahla Chaichian
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Rasoul-e-Akram Hospital, Satarkhan St
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Shahla Chaichian

Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information is available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available