

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the efficacy of surgeon assistant robot in laparoscopic ovarian cystectomy vs conventional laparoscopic ovarian cystectomy

Protocol summary

Summary

This study aims to compare objective and subjective operational related outcomes between laparoscopic ovarian cystectomies with and without robotic assistance. Laparoscopic ovarian cystectomy will be performed by entering laparoscope through three 5 mm incisions on the abdomen; then, cyst wall is removed and bleeding sites are controlled. This study is single blind randomized control trial. This trial begins from November 2010 and our time limit is up to June 2011 all patients recruited from Arash hospital. Eligible patients are those with small and moderate size cysts (3 to 10 cm), sonographically benign ovarian cysts and normal tumor markers. Patients with large size cysts, increased tumor markers and medical and surgical contraindications for laparoscopic surgery are excluded from the study. All operations will be done by trained surgeon in this field (at least 10 hour). Forty patients are equally divided into two groups. One group receives robotic assistance operation and the other human assistance. Time of operation and tiredness of the surgeon as primary outcomes and some secondary outcomes are all compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104035867N3**

Registration date: **2011-05-18, 1390/02/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-18, 1390/02/28

Registrant information

Name

Haydeh Samiee

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences(TUMS) and Sharif University of Technology

Expected recruitment start date

2010-11-15, 1389/08/24

Expected recruitment end date

2011-06-05, 1390/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of surgeon assistant robot in laparoscopic ovarian cystectomy vs conventional laparoscopic ovarian cystectomy

Public title

Comparison of the efficacy of surgeon assistant robot in laparoscopic ovarian cystectomy vs conventional laparoscopic ovarian cystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Small or middle size(3-10cm); simple,thin wall and benign ovarian cyst(s); normal

ovarian tumor markers; sonographic approval of benign cyst and trained surgeon for robotic laparoscopic surgery
Exclusion Criteria: Medical or surgical contraindication for laparoscopic surgery; elevated ovarian tumor marker(s); large size (more than 10cm)cyst and unaccepted robotic surgery by the patient

Age

From **14 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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**

Tehran university of medical sciences

Street address

6th floor,tehran university of medical sciences,Bulvar Str.

City

Tehran

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

۱۵۸۱/ ۱۳۰/ ۸۹ /۵

Health conditions studied**1****Description of health condition studied**

Ovarian cyst

ICD-10 code

N83.2

ICD-10 code description

Other and unspecified ovarian cysts

Primary outcomes**1****Description**

Tiredness of the surgeon

Timepoint

At the end of operation

Method of measurement

Desirment or undesirment to continue the procedure+
Feeling and expression of tiredness by the surgeon

2**Description**

Lenght of the operation

Timepoint

For each operation

Method of measurement

Lenght of operation from the entering of lens to the
abdomen to its removal time

Secondary outcomes**1****Description**

Frequency of undesired movement of the lens and
camera head cleaning

Timepoint

During the operation

Method of measurement

Frequency of occurrences

2**Description**

Frequency of changing robot to human assist

Timepoint

During the operation

Method of measurement

Frequency of changing

3**Description**

occupied space of the room

Timepoint

during the operation

Method of measurement

The proportion of the space occupied with system to the
entire room space

4**Description**

Frequency of lens focus correction

Timepoint

During operation

Method of measurement

Frequency of occurrences

5

Description

Responding to the surgeon's orders

Timepoint

During the operation

Method of measurement

Frequency of occurrences of proper responses and non responses

6

Description

The limitation which is produced for the surgeon

Timepoint

During the operation

Method of measurement

Frequency of limited and disrupting movements

Intervention groups

1

Description

Intervention group: Robotic laparoscopic cystectomy

Category

Treatment - Surgery

2

Description

Contro group!: Conventional laparoscopic cystectomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital affiliated to Tehran university of Medical Sciences

Full name of responsible person

Haydeh Samiee

Street address

Baghdarnia Str. Resalat high way

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arash Hospital affiliated to Tehran university of medical sciences +Sharif University of tecnology

Full name of responsible person

Dr Ashraf moini

Street address

Baghdarnia Str. , Resalat high way ,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arash Hospital affiliated to Tehran university of medical sciences +Sharif University of tecnology

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

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Haydeh Samiee

Position

Obstetrician & Gynecologist/Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Dr Haydeh Samiee

Position

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Person responsible for updating data

Contact

Name of organization / entity
TUMS
Full name of responsible person
Dr Haydeh Samiee
Position
Assistant professor
Other areas of specialty/work
Street address
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Fax
Email
Web page address

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