

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Evaluation of the effects of local- intra myometrial injection of lidocaine plus adrenaline in the amount of blood loss during myomectomy

#### Protocol summary

##### Study aim

Evaluation of the effects of intra myometrial injection of lidocaine plus adrenaline on blood loss during myomectomy

##### Design

A double-blinded, randomized clinical trial, phase 3 with parallel groups, that includes a control group, design of 60 patients.

##### Settings and conduct

This clinical trial will be done in Alzahra Hospital in Rasht, on patients candidate for myomectomy. 60 patients randomly and will be divided in two groups:(Lidocaine and adrenaline)group and control group. Medications and placebo will be prepared and coded by an anesthetic technician who is not in the research. Patients will undergo surgery through laparotomy, midline or fish-tail cut. All myomectomy cases will be performed by one surgeon with one surgical method. The same general anesthetic protocol will be considered for all patients. In this study, patients, the surgeon, as well as the trained individual who collects the information, are BLIND. Amount of bleeding will be evaluated by the difference in hemoglobin before and after the operation and the number of transfused blood units.

##### Participants/Inclusion and exclusion criteria

Entry criteria: Women of reproductive age candidate for Myomectomy Patients with symptomatic Myoma without responding to medical treatments. Non-Entry criteria: Adenomyosis of cervical myomas or peduncle Coagulation problems and recurrent vascular thrombosis Ischemic heart disease, cardiomyopathy, Women with multiple myomas

##### Intervention groups

Intervention group: In the treatment group, before the removal of the myoma, and after monitoring is done by the anesthetic team, 40 milliliters of the local anesthetic solution containing lidocaine 2% (3 milligrams per kilograms) + adrenaline 0.5 milliliters (from vial 1 milligram per milliliter) In the control group, Normal

saline is injected to the same extent.

##### Main outcome variables

Measurement of intra-operative blood loss during myomectomy

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090525001946N10**

Registration date: **2019-07-30, 1398/05/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-07-30, 1398/05/08**

Update count: **0**

##### Registration date

2019-07-30, 1398/05/08

##### Registrant information

##### Name

Mandana Mansur Ghanaie

##### Name of organization / entity

Giulan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1322 5624

##### Email address

m\_m\_ghanaie@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-07-06, 1398/04/15

##### Expected recruitment end date

2019-12-21, 1398/09/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of the effects of local- intra myometrial injection of lidocaine plus adrenaline in the amount of blood loss during myomectomy

**Public title**  
The effect of injecting of lidocaine and adrenaline in myometrium on bleeding during myomectomy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Women of reproductive age candidate for Myomectomy Patients with symptomatic Myoma without responding to medical treatments (laparotomy, infertility for more than 3 years with myomectomy indication) Pain and pelvic pressure Urination frequency and constipation The size of the uterus is less than 18 weeks. Not accepting hysterectomy Myoma grade 6-2 based on ultrasound The cause of myoma bleeding is detected

**Exclusion criteria:**  
Adenomyosis of cervical myomas or peduncle Coagulation problems and recurrent vascular thrombosis Ischemic heart disease, cardiomyopathy Women with multiple myomas Lidocaine susceptibility c Uncontrolled hypertension Hyperthyroidism Seizure Recent use of ergot alkaloids and vasoconstrictors, triangular antidepressants and monoamine oxidase inhibitors. Liver disease Diabetes, asthma, COPD Malignancy

**Age**  
No age limit

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: 60

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
To produce random sequences in this clinical trial, we will use this site:  
<http://www.graphpad.com/quickcalcs/index.cfm>. A nurse who is not in the study will do it. Patients with inclusion criteria will randomly be divided into 2 groups by quadruple block method: intervention (lidocaine and adrenaline) and control.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

Medications and placebo will be prepared and coded by an anesthetic technician who does not participate in this study. All myomectomy cases will be performed by one surgeon with one surgical method. The same general anesthetic protocol will be considered for all patients. In this study, the patient and the surgeon, as well as the trained person who collects the information and reports bleeding, are unaware of the type of treatment group and BLIND.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee Of Guilan University Of Medical Sciences

**Street address**

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street

**City**

Rasht

**Province**

Guilan

**Postal code**

4144666949

**Approval date**

2019-06-12, 1398/03/22

**Ethics committee reference number**

IR.GUMS.REC.1398.118

**Health conditions studied**

1

**Description of health condition studied**

Bleeding during myomectomy

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

The amount of bleeding of patients during myomectomy surgery

**Timepoint**

After the operation, according to the information recorded in the patient's file.

**Method of measurement**

With the difference in hemoglobin (g / dl) before and

after operation and the number of transfused blood pack cells during operation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In the treatment group, before the removal of the myoma, and after monitoring is done by the anesthetic team, 40 milliliters of the local anesthetic solution containing lidocaine 2% (3 milligrams per kilograms) + adrenaline 0.5 milliliters (from vial 1 milligram/milliliter) will be injected around Myoma and myometrium

#### Category

Prevention

### 2

#### Description

Control group: In the control group, before the removal of the myoma, and after monitoring is done by the anesthetic team, 40 milliliters of normal saline will be injected around Myoma and myometrium

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra hospital

##### Full name of responsible person

Dr mandana mansoor ghanaee

##### Street address

Opposite Shahid Azodi Stadium, Namjoo Street

##### City

Rasht

##### Province

Guilan

##### Postal code

4144654839

##### Phone

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##### Email

azzahra@gums.ac.ir

##### Web page address

<http://www.gums.ac.ir/azzahra>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Doctor Shadman Nemati

##### Street address

Vice Chancellor for research of Guilan, Shahid Siadati Avenue, Namjoo Street

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##### Province

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##### Email

drshadmannemati\_ent@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Rasht 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

Rasht University of Medical Sciences

##### Full name of responsible person

Mandana Mansur Ghanaia

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Reproduction Health Research Center-Alzahra hospital-Namjo street

##### City

Rasht

##### Province

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

Rasht University of Medical Sciences

**Full name of responsible person**

Mandana Mansur Ghanaie

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Reproduction Health Research Center-Alzahra

hospital-Namjo street

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**Province**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Mohadese Ahmadi

**Position**

Research Expert/(MSc) English

**Latest degree**

Master

**Other areas of specialty/work**

Research Expert

**Street address**

Anesthesiology Reseaech Center, Alzahra Hospital,

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p.ahmadi2311@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available