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

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Name of organization / entity
Giulan University of Medical Sciences

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Doctor Shadman Nemati

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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
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 Ghanaie

Position
Assistant professor

Latest degree
Specialist

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)
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