Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The evaluation of intraarterial lidocaine injection during uterine artery embolization on the reduction of post-embolization pain

Protocol summary

Study aim
Determination of intraarterial lidocaine injection during uterine artery embolization on post-embolization pain reduction

Design
The randomized clinical trial contains a control group with parallel groups in phase 2-3 on 50 patients. The randomization will be done using the envelopes containing randomized numbers.

Settings and conduct
The study will be conducted on the candidate patients for uterine artery embolization for uterine fibroma embolization. The patients will be operated by obstetrics and gynecology specialists. During the surgical procedure, the intervention group will receive bilateral intra-uterine artery lidocaine, while the case group will not. The patients and the statistician will be blinded to the intervention. The patients are unaware of the injection; however, they will be informed about it in advance to the intervention and sign written consent. The data will be provided to the statistician as numbers 1 and 2.

Participants/Inclusion and exclusion criteria
Inclusion criteria: -The patients with confirmed leiomyoma by ultrasonography -Being in the childbearing ages Exclusion criteria: -The patients with a medical history of hypersensitivity to pethidine, morphine, lidocaine, and contrast agents -The history of cardiac arrhythmia -The presence of active pelvic inflammatory disease

Intervention groups
The candidate patients for uterine artery embolization during uterine fibroma embolization will be randomly assigned into two control and intervention groups. The embolization procedure and all the parameters during the surgery will be similar in the two groups, except that the intervention group will receive an intraarterial injection of 5 cc lidocaine 1% (50 mg), while the controls will not.

Main outcome variables
Postoperative pain; pethidine dose

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220126053835N1**
Registration date: **2022-08-08, 1401/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-08, 1401/05/17**
Update count: **0**
Registration date
2022-08-08, 1401/05/17

Registrant information
Name
Reza Tabibian
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3250 6157
Email address
srt_1371@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-07-06, 1401/04/15
Expected recruitment end date
2022-09-06, 1401/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The evaluation of intraarterial lidocaine injection during uterine artery embolization on the reduction of post-embolization pain

Public title
Effect of intraarterial lidocaine on post uterine fibroma embolization pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patients with confirmed leiomyoma by ultrasonography Being in the childbearing ages Being the candidate of uterine artery embolization according to the opinion of obstetrician and gynecology specialist

Exclusion criteria:
The patients with medical history of hypersentivity to pethidine, morphine, lidocaine and contrast agents The history of cardiac arrhythmia The presence of active pelvic inflammatory disease

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients who meet the study criteria will enter the study through simple convenience sampling. A simple randomization method with individual blocks will be applied in the current study using blinded envelopes. Accordingly, each envelope contains a number about which the patient and the person who will gather the data will be blinded, and the patient will be allocated to one of the case versus control groups considering the number in the envelope. If the number is odd, the patient will be allocated to the intervention group and, if even, to the case group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the anesthesia of the participants, they will be blinded to the performed arterial intervention for them. Albeit, they will get aware of the procedures in advance of the interventions and will sign a written consent. The statistical analyzer will be blinded, as well, because the data will be provided to him as group 1 and 2.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-12-04, 1399/09/14

Ethics committee reference number
IR.MUI.MED.REC.1399.793

Health conditions studied

1

Description of health condition studied
Post-uterine artery embolization pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Postoperative pain

Timepoint
2, 4, 6 and 8 hours after the operation

Method of measurement
Visual Analogue Scale

2

Description
The applied pethidine dosage for pain controlling

Timepoint
2, 4, 6 and 8 hours after the operaion

Method of measurement
According to the medical records (mg)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patients will be sedated with 5 mg midazolam and the embolization process will be initiated. The standard embolization protocol will be applied in which a 5 f catheter will be used to embolize through internal iliac artery by an expert interventionist. The embolization will be performed using polyvinyl alcohol entering through the horizontal part of uterine artery by a microcatheter. During the process of embolization, 5 cc lidocaine 1% (50 mg) will be injected.
Category
Treatment - Drugs

2

Description
Control group: The patients will be sedated with 5 mg midazolam and the embolization process will be initiated. The standard embolization protocol will be applied in which a 5 f catheter will be used to embolize through internal iliac artery by an expert interventionist. The embolization will be performed using polyvinyl alcohol entering through the horizontal part of the uterine artery by a microcatheter. The control group will not recieve any other injection.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Reza Tabibian
Street address
Isfahan University of Medical Sciences, Shohada-ye-Sofe Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3668 5555
Email
Srt_1371@yahoo.com

2

Recruitment center
Name of recruitment center
Khorshid Hospital
Full name of responsible person
Reza Tabibian
Street address
Khorshid Hospital, Ostandari Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8145831451
Phone
+98 31 3222 2127
Email
Srt_1371@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mozhgan Mortazavi
Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3668 0048
Email
mortazavi@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Reza Tabibian
Position

Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiology
Street address
No.30, 12 Ave, south Farsan street
City
Isfahan
Province
Isfehan
Postal code
8196837960
Phone
+98 31 3250 6157
Fax
Email
srt_1371@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Reza Tabibian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiology
Street address
No.30, 12 Ave, south Farsan street
City
Isfahan
Province
Isfehan
Postal code
8196837960
Phone
+98 31 3250 6157
Fax
Email
srt_1371@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Reza Tabibian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiology
Street address
No.30, 12 Ave, south Farsan street
City
Isfahan
Province
Isfehan
Postal code
8196837960
Phone
+98 31 3250 6157
Fax
Email
srt_1371@yahoo.com

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
All data is potentially shareable after de-identifying the participants
When the data will become available and for how long
The data might be accessible within 6 months after the article publication
To whom data/document is available
The university teachers can access the data
Under which criteria data/document could be used
the data might be accessible for the future researches and through official requests.
From where data/document is obtainable
The author who is responsible for the study should be emailed. Dr. Reza Tabibian Srt_1371@yahoo.com
What processes are involved for a request to access data/document
If the person who requires data would email the author and represent the proposal of the study and the organization who is responsible for the study performance would be clear, the data are accessible.
Comments