

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

comparison the outcome of hystroscopic myomectomy with and without vasopressin injection in women with submucosal myoma

Protocol summary

Study aim

define and compare the average of Hb decrease and the duration of surgery and hospitalized days and to define the amount of deficit fluid, electrolyte imbalance and the size of myoma in hystroscopical myomectomy by injecting vasopressin and without injecting vasopressin

Design

This study is a one_side_blind randomized clinical trial. The way of sampling is simple. In this study the patients who are candidates for hystroscopical myomectomy are divided into 2 groups accidentally, there are 22 people in each group. One group will receive transcervical intralesion vasopressin and the second group won't receive any drug.

Settings and conduct

The first group will have a surgery called conventional hysteroscopic myomectomy, and the second group will have hysteroscopic myomectomy surgery with injecting vasopressin. In this study 20 unit vasopressin is diluted in 60 cc normal salin to have .1 unit in 1 cc. Then 3 cc is injected in 3 points by needle injection around the myoma, and after that the resection of the myoma will be begin. The blood sample is taken in order to check the amount of Hb decrease and electrolyte imbalance 4 hours after the surgery.

Participants/Inclusion and exclusion criteria

the women 18 to 62 years old and had given permission to be studied. In all the patients the existence of the submucosal myoma was approved by sonography or hysteroscopy. the people who expired during the surgery are out of the study.

Intervention groups

The patients are divided accidentally into two groups,. The first group will have hysteroscopic myomectomy with vasopressin, the placebo group without vasopressin.

Main outcome variables

Comparing the average of Hb decrease, duration of surgery, hospitalized days, average of deficite volume, electrolyte imbalances and the size of myoma.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120201008897N6**

Registration date: **2018-05-29, 1397/03/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-29, 1397/03/08**

Update count: **0**

Registration date

2018-05-29, 1397/03/08

Registrant information

Name

Safoura Rouholamin

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-30, 1396/02/10

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the outcome of hystroscopic myomectomy with and without vasopressin injection in women with submucosal myoma

Public title

The effect of vasopressin on outcome of hystroscopic myomectomy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

women in 18 years old until 62 years old who has submucosal myoma in all of them the existence of submucosal myoma was approved The women have the testimonial

Exclusion criteria:

those who have died during surgery

Age

From **18 years** old to **62 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

people are accidentally divided in two groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study the patients, outcome assessor and data analyser don't know which participant has received vasopressin and which one has received the placebo.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Esfahan University of Medical Sciences

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Isfahan University of Medical Sciences, Hezarjerib Street

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1417614411

Approval date

2017-04-22, 1396/02/02

Ethics committee reference number

IR.MUI.REC.1396.3.113

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

Hysterescopic myomectomy

ICD-10 code

D25.0

ICD-10 code description

Submucous leiomyoma of uterus

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

Hb decrease

Timepoint

the day after surgery

Method of measurement

kit lab

2**Description**

hyponatremia

Timepoint

the day after surgery

Method of measurement

kit lab

3**Description**

hypo kalemia

Timepoint

the day after surgery

Method of measurement

kit lab

4**Description**

deficite volume

Timepoint

after the ending of surgery

Method of measurement

surgeon 's estimate

5**Description**

the length of surgery
Timepoint
duration of surgery
Method of measurement
minutes

6

Description
hospitalised day
Timepoint
hospitalized duration
Method of measurement
counting day

7

Description
size of myoma
Timepoint
during surgery
Method of measurement
cheklist

Secondary outcomes

empty

Intervention groups

1

Description
hystroscopic myomectomy with vasopressin
Category
Treatment - Surgery

2

Description
hystroscopic myomectomy without vasopressin
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Web page address
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

Sara Haghshenas

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Position

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Review the complications of hysteroscopic myomectomy with and without vasopressin

When the data will become available and for how

long

The time of accessibility is a month after publishing the information

To whom data/document is available

The information is available for everyone

Under which criteria data/document could be used

The information is available for everyone and everyone is allowed to do any kind of analyses on them

From where data/document is obtainable

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code:1417614411 phone:00983136202020

website://alzahra.mui.ac.ir Dr Safoura Rouholamin

What processes are involved for a request to access data/document

The demandant should send her/his name, occupation, field of study and purpose in an email. The requested information will be sent in a week.

Comments