Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Evaluation of the outcome of previous cesarean scar pregnancy after laparoscopic surgery

Protocol summary

Study aim
Determination of the laparoscopic surgery on the management of cesarean scar pregnancy
Design
A non-randomized clinical trial, with the single group
Settings and conduct
In this study, 38 patients with cesarean scar pregnancy are included in the study. Due to having only one treatment group, there is no blinding. These patients undergo laparoscopy. So that during laparoscopy, the bladder peritoneum separates from the lower uterine segment, and resection of the gestational sac is performed. Myometrial thickness, isthmocele prevalence, and the prevalence of abnormal postoperative bleeding will be recorded.
Participants/Inclusion and exclusion criteria
Inclusion criteria include confirmation of cesarean scar pregnancy based on ultrasound criteria and consent to participate in the study. Exclusion criteria are unstable hemodynamic symptoms.
Intervention groups
In this study, patients undergo laparoscopy surgery. During laparoscopy, the bladder peritoneum separates from the lower uterine segment, and resection of the gestational sac is performed.
Main outcome variables
Myometrial thickness; Isthmocele prevalence; Prevalence of abnormal postoperative bleeding

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120201008897N8**
Registration date: **2020-12-14, 1399/09/24**
Registration timing: **prospective**
Last update: **2020-12-14, 1399/09/24**
Update count: **0**
Registration date
2020-12-14, 1399/09/24

Registrant information
Name
Safoura Rouholamin
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 1236 7001
Email address
s_rouholamin@med.mui.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-12-21, 1399/10/01
Expected recruitment end date
2021-06-21, 1400/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the outcome of previous cesarean scar pregnancy after laparoscopic surgery

Public title
Evaluation of the efficacy of laparoscopic for the management of cesarean scar pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Confirmation of pregnancy at the site of cesarean scar based on ultrasound criteria Consent to participate in the study
Exclusion criteria:
Having unstable hemodynamic symptoms

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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, Hezarjerib Street

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2020-07-30, 1399/05/09

Ethics committee reference number
IR.MUI.MED.REC.1399.348

Health conditions studied

1

Description of health condition studied
Cesarean scar pregnancy

ICD-10 code
O34.21

ICD-10 code description
Maternal care for scar from previous cesarean delivery

Primary outcomes

1

Description
Myometrial thickness

Timepoint
Three months after laparoscopy

Method of measurement
Sonography

2

Description
Isthmocele

Timepoint
Three months after laparoscopy

Method of measurement
Sonography

Secondary outcomes

1

Description
Abnormal bleeding

Timepoint
6months after laparoscopy

Method of measurement
Observation

Intervention groups

1

Description
Intervention group: In this study, patients undergo laparoscopy surgery. During laparoscopy, the bladder peritoneum separates from the lower uterine segment, and resection of the gestational sac is performed.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital

Full name of responsible person
Safoura Rouholamin

Street address
Department of Obstetrics and Gynecology, Al-Zahra Hospital, Sofeh Blvd., Tohid Street

City
Isfahan

Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
s_rouholamin@med.mui.ac.ir

2

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Safoura Rouholamin
Street address
Obstetrics and Gynecology Department, Kashani Hospital, Kashani Street.
City
Isfahan
Province
Isfehan
Postal code
8183983434
Phone
+98 31 3233 0091
Email
s_rouholamin@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Safoura Rouholamin
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Beheshti hospital, Felezi bridge
City
Isfahan
Province
Isfehan
Postal code
8139946535
Phone
+98 31123670015
Fax
Email
s_rouholamin@med.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Safoura Rouholamin
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Beheshti hospital, felezi bridge
City
Isfahan
Province
Isfehan
Postal code
8139946535
Phone
+98 31123670015
Fax

Email
s_rouholamin@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Nasrin Ghasemi
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Beheshti hospital, Felezi bridge
City
Isfahan
Province
Isfehan
Postal code
8139946535
Phone
+98 31 2367 0015
Fax
Email
drnasrin63@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available