Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of three treatment methods in incisional pregnancy: methotrexate intrasac injection and potassium chloride intrasac injection and hysteroscopic resection

Protocol summary

Study aim

Comparison of three treatment methods in incisional pregnancy: methotrexate intrasac injection and potassium chloride intrasac injection under ultrasound guidance and hysteroscopic resection

Design

A randomized clinical trial with 3 parallel-groups, single-blind, design of 15 patients will be enrolled. The rand function of Excel software will be used for randomization.

Settings and conduct

This study is conducted in Al-Zahra level 3 referral Hospital in Tabriz, ,and all patients diagnosed with cesarean scar pregnancy and meeting the study criteria are included in the study.

Participants/Inclusion and exclusion criteria

IC: Definitive diagnosis of incisional pregnancy Stable hemodynamic status Absence of severe vaginal bleeding Consent to participate in the study Pregnancy less than 10 weeks EC: History of drug sensitivity History of blood disorders Having liver disorders Having pulmonary disorders

Intervention groups

Intervention group (IG) 1: injection, into the sac and if the heartbeat is seen, into the heart of the fetus, of methotrexate in the amount of 1.5 square centimeters from an ampoule of 50 mg per 2 square centimeters. These patients will undergo curettage the next day under transabdominal ultrasound. (IG) 2: Intervention group: injection, into the sac and if the heartbeat is seen, into the heart of the fetus, of KCL in the amount of 1.5 square centimeters of a 15% solution. These patients will undergo curettage the next day under transabdominal ultrasound. (IG) 3: After injecting 1 mg per square meter of intramuscular methotrexate, they will undergo hysteroscopic resection of cesarean scar pregnancy the next day.

Main outcome variables

The primary outcome of the study is the successful treatment of patients, which is characterized by the reduction of serum b-hCG levels until they become negative and the observation of an empty uterus by transvaginal ultrasound.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101227005485N10**
Registration date: **2023-01-06, 1401/10/16**
Registration timing: **prospective**

Last update: **2023-01-06, 1401/10/16**
Update count: **0**

Registration date

2023-01-06, 1401/10/16

Registrant information

Name

Nazli Navali

Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medecine

Country

Iran (Islamic Republic of)

Phone

+98 41 1330 2879

Email address

navalin@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date
2023-12-31, 1402/10/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of three treatment methods in incisional pregnancy: methotrexate intrasac injection and potassium chloride intrasac injection and hysteroscopic resection

Public title
Comparison of three treatment methods in incisional pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of incisional pregnancy Stable hemodynamic status Absence of severe vaginal bleeding Consent to participate in the study Pregnancy less than 10 weeks
Exclusion criteria:
History of drug sensitivity History of blood disorders Having liver disorders Having pulmonary disorders
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the participants are unaware of the type of treatment they will receive.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Research Deputy of Tabriz University of Medical Sciences, University of Tabriz, Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2022-08-01, 1401/05/10
Ethics committee reference number
IR.TBZMED.REC.1401.422

Health conditions studied

1

Description of health condition studied
cesarean scar
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The primary outcome of the study is the successful treatment of patients, which is the reduction of serum b-hCG levels until it become negative.
Timepoint
Every week
Method of measurement
Radioimmunoassay

2

Description
The primary outcome of the study is the successful treatment of patients, by confirming the empty uterus on the ultrasound exam.
Timepoint
Every mounth
Method of measurement
Transvaginal sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: injection of methotrexate in the amount of 1.5 square centimeters from an ampoule of 50 mg per 2 square centimeters from Daro Derman Pars Company into the sac or if the heartbeat exist, into the heart of the fetus. These patients will undergo curettage the next day, under transabdominal ultrasound control.

Category

Treatment - Surgery

2

Description

Intervention group: injection of KCL in the amount of 1.5 square centimeters of 15% solution made by the Pasteur Institute (equivalent to 3 milliequivalents), into the sac or if the heartbeat exist, into the heart of the fetus. These patients will undergo curettage the next day under transabdominal ultrasound control.

Category

Treatment - Surgery

3

Description

Intervention group: After a day of injecting 1 mg per square meter of intramuscular methotrexate, they will undergo hysteroscopic resection of cesarean scar pregnancy.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Navali Nazli

Street address

South Artesh

City

Tabriz

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5138665793

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navalin@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

dr. Laya Farzadi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Nazli Navali

Position

infertility fellowship/associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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