

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 randomization 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 Medicine

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

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Tabriz

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5138665793

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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

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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