

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Safety and effectiveness of preoperative progressive pneumoperitoneum and botulinum toxin administration before abdominal wall reconstruction in patients with complex ventral hernia with loss of domain.

Protocol summary

Study aim

Determining safety and effectiveness of preoperative progressive pneumoperitoneum and botulinum toxin administration before abdominal wall reconstruction in patients with complex ventral hernia with loss of domain.

Design

This study is a phase 2 clinical trial without a control group that will be conducted on 10 patients.

Settings and conduct

Patients who were referred to Ghaem Hospital in Mashhad for abdominal wall hernia reconstruction will be included. The volume of the abdominal cavity and incisional hernia will be measured. There is no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Abdominal incisional hernia with loss of domain Referring to abdominal wall reconstructive surgery. Exclusion criteria: Unwillingness to participate in the study. A history of allergy to Botox.

Intervention groups

500 units of botulinum A (Masport, MasoonDarou Pharmaceutical Company, Iran) are mixed in 50 ml of normal saline. Under ultrasound guidance, it is injected in three layers of internal, external, and transverse oblique muscle in the abdominal wall and in 10 areas. The patient will be subjected to prep and drape in the same session for pneumoperitoneum. A small incision is made 5 cm from the herniated area, then the abdominal wall muscles are opened. Then, an 8-French feeding tube catheter is inserted into the peritoneum. Then the small incision is repaired, and the catheter is sutured to the abdominal wall. Finally, air injection starts in the amount of 1000 to 1500 ml in the first day. In the following days, the amount of air injection will be increased or decreased to such an extent that it does not cause discomfort, pain, or shortness of breath. The procedure will be performed in one session. After 1 month, the abdominal cavity and

incisional hernia volume will be measured.

Main outcome variables

The volume of the abdominal cavity, Hernia volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230408057846N1**

Registration date: **2023-06-18, 1402/03/28**

Registration timing: **retrospective**

Last update: **2023-06-18, 1402/03/28**

Update count: **0**

Registration date

2023-06-18, 1402/03/28

Registrant information

Name

Mohammad Reza Yousefi Rudsari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3833 2043

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and effectiveness of preoperative progressive pneumoperitoneum and botulinum toxin administration before abdominal wall reconstruction in patients with complex ventral hernia with loss of domain.

Public title

Administration of pneumoperitoneum and botulinum toxin in abdominal wall reconstruction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Abdominal incisional hernia with loss of domain Referring for abdominal wall reconstructive surgery

Exclusion criteria:

Unwillingness to participate in the study. A history of allergy to Botox.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 10

Randomization (investigator's opinion)

N/A

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**

Research Ethics Committees of Imam Reza Hospital Educational, Research and Treatment Center- Mashhad

Street address

Shahrak Danesh va Salamat, Shahid Fakouri Blvd. City. Mashhad.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.MUMS.IRH.REC.1401.067

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

Large abdominal wall hernia with loss of domain

ICD-10 code

K46.9

ICD-10 code description

Unspecified abdominal hernia without obstruction or gangrene

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

The volume of the abdominal cavity

Timepoint

Before and one month after botulinum and pneumoperitoneum injection

Method of measurement

Measurement of the the abdominal cavity volume by CT scan

2**Description**

Hernia volume

Timepoint

Before and one month after botulinum and pneumoperitoneum injection

Method of measurement

Measurement of the the hernia volume by CT scan

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 500 units of botulinum A (Masport, MasoonDarou Pharmaceutical Company, Iran) are mixed in 50 ml of normal saline. Under ultrasound guidance, it is injected in three layers of internal, external, and transverse oblique muscle in the abdominal wall and in 10 areas. The patient will be subjected to prep and drape in the same session for pneumoperitoneum. A small incision is made 5 cm from the herniated area, then the

abdominal wall muscles are opened. Then, an 8-French feeding tube catheter is inserted into the peritoneum. Then the small incision is repaired, and the catheter is sutured to the abdominal wall. Finally, air injection starts in the amount of 1000 to 1500 ml in the first day. In the following days, the amount of air injection will be increased or decreased to such an extent that it does not cause discomfort, pain, or shortness of breath. The procedure will be performed in one session. After 1 month, the abdominal cavity and incisional hernia volume will be measured.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem hospittal

Full name of responsible person

Ghodratollah Maddah

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Reza Yousefi Rudsari

Position

Radiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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