Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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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Parastar Street, Ahmadabad Blvd

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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

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Person responsible for updating data

Contact

Name of organization / entity
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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