

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Combination of midurethral sling vs low-dose dysport injection in comparison with midurethral sling alone in mixed incontinence

Protocol summary

Study aim

Midraethral sling combination and low dose dysport injection compared to sling alone in combined urinary incontinence

Design

In this double-blind, randomized clinical controlled trial, 10 patients were randomly selected as the intervention group based on computerized blocking system and underwent sling surgery with simultaneous injection of 500 units of dysport, and 10 patients as control group underwent sling surgery alone.

Settings and conduct

Patients will be evaluated and evaluated for response to treatment at 1 month and 3 months after surgery. The treatment evaluation in this study will be based on ICIQ and ICIQ-OAB questionnaires. This study uses blinding techniques to prevent bias as much as possible. This is because the surgeon is not aware of the patient's name and the person responsible for completing the questionnaire will be unaware of which patient is in which group.

Participants/Inclusion and exclusion criteria

In this study, 20 patients with combined urinary incontinence who did not respond to drug therapy will be enrolled. Everyone will be examined and given a history. Patients with hypertrophic urethra, severe prolapse, neurogenic disease (MS, CVA, etc.) and patients with a history of abdominal surgery are excluded. The rest will be urodynamic and patients with VLPP + + D.O, Cough induced D.O + leakage, and Capacity normal or average will be included in the study.

Intervention groups

In this study, 10 patients underwent TOT surgery with 500 Dysport injections and the rest of the patients will undergo TOT surgery alone.

Main outcome variables

Comparison of response rate to treatment of urinary incontinence in two methods

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130306012728N7**

Registration date: **2020-03-01, 1398/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-01, 1398/12/11**

Update count: **0**

Registration date

2020-03-01, 1398/12/11

Registrant information

Name

Sakineh Hajebrahimi

Name of organization / entity

Urology Department, Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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ebrahimis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combination of midurethral sling vs low-dose dysport injection in comparison with midurethral sling alone in mixed incontinence

Public title

effect of dysport in addition to surgery of incontinence

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

mixed urinary incontinence with no response to drugs
Patients with VLPP+ + D.O.Cough induced D.O +
Leakage , Capacity normal or average in urodynamic study

Exclusion criteria:

urethral hyper mobility severe prolapse neurological diseases (CVA,MS,..) previous abdominal surgeries

Age

From **15 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Patients will be randomly divided into intervention and control groups using random number table based on file number.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Tabriz University of Medical Sciences

Street address

Azadi St. Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5385137813

Approval date

2019-09-27, 1398/07/05

Ethics committee reference number

IR.TBZMED.REC.1398.705

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

mixed Urinary incontinence

ICD-10 code

N39.46

ICD-10 code description

Mixed incontinence

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

Urinary incontinence complaints are one of the most common urological complaints, especially among women, with a prevalence of around 12-17%.

Timepoint

Patients will be evaluated and evaluated for response to treatment at 1 and 3 months after surgery.

Method of measurement

The treatment response assessment method will be based on ICIQ and ICIQ-OAB questionnaires.

Secondary outcomes

empty

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

Intervention group: undergo sling surgery with simultaneous injection of 500 units of Dysport.

Category

Treatment - Surgery

2**Description**

Control group: undergo sling surgery alone

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Emam Reza hospital

Full name of responsible person

Hooshang Shamsi Sisi

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Azadi St. Golgasht Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

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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

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

Hooshang Shamsi Sisi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available