

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the Effects of Modified Combined-Modality Treatment approach with Botox-Injection on Voices of Patients with Adductor Spasmodic Dysphonia

Protocol summary

Summary

Objective: To evaluate the effects of combined modality therapy on patients with spasmodic dysphonia voice and comparison with Botox alone Inclusion and exclusion criteria: All patients with a diagnosis of spasmodic dysphonia and no history of Botox injections are enrolled. Patients with a history of neurological disorders or symptoms of dystonia in other areas of the body are excluded. Study Type: Parallel- single blind- Randomized clinical trial Sample size: Patients with spasmodic dysphonia admitted to Amir-alam hospital - 10 patients' allocated to intervention and control groups. Interventions: Both groups of patients undergoing Botox injections. Ten Semi-intensive Voice Therapy sessions administered to patients in interventional group. A comprehensive voice assessment will be done at following time points: before injection, 1, 3 and 6 months after injection. Time of interventions: Voice Therapy starts immediately after the injection in the intervention group. If Voice Therapy proved sufficient in intervention group, patients in the control will enrolled to Voice Therapy in order to eliminate the effects of treatment deprivation, at the end of the study. Primary outcome: It is expected that all patients benefit more comfortable phonation process after injection ; and after the Voice Therapy sessions, patients in the intervention group expected to achieve a better voice quality. Study: Randomized Clinical Trial – Parallel - Single blind Participants: all ADSD patients referred to Amir-Alam hospital- 10 patients with ADSD will randomly assigned to the interventional and control groups. Method: Both groups will go under Botox injection. After injections, patients in intervention group will have 10 semi-intensive sessions of Voice Therapy. All patients' voices will be assessed before injections, 1-3-and 6 months after injection. Interventional Timing: Voice Therapy sessions will be begin 2 days after injection in intervention group.

Patients in Control group will receive all Voice Therapy techniques and sessions if the positive effects will be identified after 6 months. Primary outcome: We expect all patients experience more comfortable phonation, after Botox injection; and also in patients in interventional group, have a better voice quality after following Voice Therapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122926499N2**

Registration date: **2017-01-16, 1395/10/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-16, 1395/10/27

Registrant information

Name

Maryam Faham

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3636 3054

Email address

mfaham@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences (IUMS)

Expected recruitment start date

2016-11-21, 1395/09/01
Expected recruitment end date
2017-11-22, 1396/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison the Effects of Modified Combined-Modality Treatment approach with Botox-Injection on Voices of Patients with Adductor Spasmodic Dysphonia

Public title

The effect of voice therapy on treatment of patients with spasmodic dysphonia after Botox injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: all patients with adductor Spasmodic Dysphonia; No history of Botox injection Exclusion: presence of any progressive CNS disorders; Dystonic signs in other part of the body

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences(IUMS)

Street address

IUMS Central Building, Hemmat highway

City

Tehran

Postal code

Approval date

2016-11-07, 1395/08/17

Ethics committee reference number

IR.IUMS.REC 1395-9221363204

Health conditions studied

1

Description of health condition studied

Adductor Spasmodic Dysphonia

ICD-10 code

R49.8

ICD-10 code description

Other and unspecified voice disturbances

2

Description of health condition studied

Adductor Spasmodic Dysphonia

ICD-10 code

G 24.4

ICD-10 code description

Idiopathic and orofacial dystonia,

Primary outcomes

1

Description

Jitter

Timepoint

before intervention, 1-3-6 months after intervention

Method of measurement

Praat software, Hertz

2

Description

Fundamental Frequency

Timepoint

before intervention, 1-3-6 months after intervention

Method of measurement

Praat software, Hertz

3

Description

Shimmer

Timepoint

before intervention, 1-3-6 months after intervention

Method of measurement

Praat software, Percent

4

Description

Maximum Phonation Time

Timepoint

before intervention, 1-3-6 months after intervention

Method of measurement

Timer, Second

5

Description

Perceptual Voice Quality

Timepoint

before intervention, 1-3-6 months after intervention

Method of measurement

GRBAS scale

6

Description

Voice Self-assessment score

Timepoint

before intervention, 1-3-6 months after intervention

Method of measurement

Voice Activity and Participation Profile- Persian Version

Secondary outcomes

1

Description

Between Injections intervals

Timepoint

6 month after intervention

Method of measurement

Month

Intervention groups

1

Description

Intervention group: Combined0modality approach which consists of Botox injection and 10 Semi-intensive Voice Therapy. Each session lasts for 30 minutes. The injection will apply bilaterally to both Thyroaryteniod Muscles. Voice Therapy methods are as bellows: Voice hygiene, Jacobson Relaxation Technique, Laryngeal Massage, Smith accent Method, some parts of LMRVT, Inhalation phonation, Easy Onset Phonation

Category

Rehabilitation

2

Description

Control Group: They receive Botox injection. Both Thyroarytenoid muscles will be injected. They will not recieve any Voice THERapy after injection.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

AmirAlam hospital complex

Full name of responsible person

Peyman Dabirmoghadam

Street address

Sa'adi street, Enqelab Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Ali-Javad Musavi

Street address

IUMS central Building, Hemmat Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences (IUMS)

Full name of responsible person

Maryam Faham

Position

Ph.D candidate in Speech and Language Pathology

Other areas of specialty/work

Street address

Rehabilitation Sciences School, Madadkaran Alley, Mirdamad Bulvd

City

Tehran

Postal code

15875-4391

Phone

+98 21 2222 8051

Fax

+98 21 2222 0946

Email

Mfaham@iums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farhad Torabinezhad

Position

Ph.d, Assistant Professor

Other areas of specialty/work

Street address

Rehabilitation Sciences School, Madadkaran Alley,
Mirdamad Bulvd

City

Tehran

Postal code

15875-4391

Phone

+98 21 2222 8051

Fax

+98 21 2222 0946

Email

ftorabi@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Faham

Position

Ph.D candidate in Speech and Language Pathology

Other areas of specialty/work

Street address

Rehabilitation Sciences School, Madadkaran Alley,
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+98 21 2222 8051

Fax

+98 21 2222 0946

Email

Mfaham@iums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty