Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effect of mesobotox injection on one side of the body compared to the contralateral side in patients with hidradenitis suppurativa receiving biologic therapy

Protocol summary

Study aim

To assess the efficacy and safety of intradermal botulinum toxin injection in hidradenitis suppurativa compared to non-interventional control in a split-body design

Design

Randomized, single-blind, within-person controlled, split-body clinical trial, phase 2/3, conducted on 20 patients with hidradenitis suppurativa. Random allocation of the intervention side is performed using block randomization with allocation concealment using sealed envelopes.

Settings and conduct

This study is conducted at the dermatology clinic of Razi Hospital. Eligible patients are enrolled after obtaining written informed consent. In each patient, one side is randomly assigned to receive intradermal mesobotox injection, while the contralateral side serves as a non-interventional control. Patients are blinded to the allocated intervention side. Clinical outcomes including treatment response, pain intensity and quality of life are evaluated at baseline, 8 weeks post-intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age ≥18; bilateral symmetrical hidradenitis suppurativa; written informed consent. Exclusion criteria: Toxin hypersensitivity; neuromuscular disorders; pregnancy/lactation; prior botulinum toxin or surgery in the area (<6 months); severe active infection needing urgent drainage

Intervention groups

Intervention group: Intradermal injection of mesobotox into hidradenitis suppurativa lesions and affected areas. Control group: No intervention or injection is administered on the contralateral side.

Main outcome variables

At least a 50% reduction in the total inflammatory nodule and abscess count, with no increase in the number of abscesses or draining fistulas. Time points: Baseline 8, weeks post-intervention assessed by clinical examination.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241115063720N2**
Registration date: **2026-09-29, 1405/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-29, 1405/07/07**
Update count: **0**

Registration date

2026-09-29, 1405/07/07

Registrant information

Name

Toomaj Shahverdi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 66 4230 2523

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-09-21, 1405/06/30

Expected recruitment end date

2026-10-12, 1405/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of mesobotox injection on one side of the body compared to the contralateral side in patients with hidradenitis suppurativa receiving biologic therapy

Public title

Evaluating the efficacy of mesobotox injection in improving skin lesions in patients with hidradenitis suppurativa

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and older Definite diagnosis of moderate-to-severe hidradenitis suppurativa (Hurley stage II or III) Presence of bilateral and relatively symmetrical active inflammatory lesions Receiving a stable dose of biologic therapy for at least 12 weeks prior to study Informed consent to participate in the study

Exclusion criteria:

Known hypersensitivity to botulinum toxin or any of its components Underlying neuromuscular disorders such as myasthenia gravis or Lambert-Eaton syndrome Pregnancy or lactation Active acute cutaneous infection or cellulitis at the injection sites Patient unwillingness to continue participation at any stage of the study

Age

No age limit

Gender

Male

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this split-body trial, the allocation of the intervention side (right or left side of the body) to receive mesobotox or placebo is performed using block randomization generated by statistical software. Allocation concealment is ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). Syringes containing mesobotox and normal saline with identical appearance and volume are prepared and coded by an independent person not involved in patient outcome assessment.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this split-body trial, the study is conducted in a single-blind manner where only the participant (patient) is blinded to the intervention side. Clinical lesion evaluations and outcome assessments are performed by the investigator physician, and no placebo is administered on the control side.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Central Building, Corner of Poursina St., Qods St., Enghelab Ave., Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۶۵۳۷۶۱

Approval date

2026-04-25, 1405/02/05

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1405.059

Health conditions studied

1

Description of health condition studied

Hidradenitis Suppurativa

ICD-10 code

L73.2

ICD-10 code description

Hidradenitis suppurativa

Primary outcomes

1

Description

Clinical response defined by Hidradenitis Suppurativa Clinical Response (HiSCR), which is at least a 50% reduction in total inflammatory nodule and abscess count with no increase in abscess or draining tunnel count.

Timepoint

Before the intervention and 8 weeks later

Method of measurement

Clinical physical examination by a dermatologist to count inflammatory nodules, abscesses, and draining tunnels/fistulas, followed by calculation and evaluation of Hidradenitis Suppurativa Clinical Response (HiSCR)

achievement.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intradermal injection of botulinum toxin type A (mesobotox technique) into lesions and affected anatomical areas of hidradenitis suppurativa. Injections are administered intradermally in a single session using a fine needle
Category
Treatment - Drugs

2

Description
No injection or placebo is administered on the contralateral control side, and the patient only receives routine standard care and follow-up clinical assessments for comparison.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Toomaj Shahverdi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Toomaj Shahverdi
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the confidentiality of patients' medical data
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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