Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Evaluation of Changes in Clinical Severity and Inflammatory Biomarkers in Hidradenitis Suppurativa Patients Receiving Infliximab With Versus Without Adjunctive Tirzepatide (Spartina) Therapy

Protocol summary

Study aim

To compare the efficacy of adding Tirzepatide to Infliximab versus Infliximab alone on clinical severity, particularly Hidradenitis Suppurativa Clinical Response (HiSCR), and inflammatory biomarkers in patients with moderate-to-severe Hidradenitis Suppurativa over 24 weeks

Design

Phase 2, open-label, parallel-group, randomized controlled clinical trial on 20 patients. Simple randomization (1:1 ratio) will be used

Settings and conduct

The study will be conducted at Razi Hospital, affiliated with Tehran University of Medical Sciences. It is an open-label trial without blinding. Patients will be evaluated clinically at weeks 0, 8, 16, and 24

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years; Hidradenitis Suppurativa at Hurley Stage II or III; Body Mass Index (BMI) >= 27; receiving stable Infliximab therapy for at least 12 weeks; written informed consent. Exclusion criteria: Personal or family history of Medullary Thyroid Carcinoma (MTC); Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); history of pancreatitis; diabetic retinopathy; pregnancy or breastfeeding; active malignancy; severe renal failure

Intervention groups

Intervention group: Subcutaneous injection of Tirzepatide (dose escalating from 2.5 to 7.5 mg/week) plus standard Infliximab therapy. Control group: Standard Infliximab therapy alone without placebo

Main outcome variables

Achievement of Hidradenitis Suppurativa Clinical Response (HiSCR) at week 24, assessed by clinical examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230502058057N2**
Registration date: **2026-09-24, 1405/07/02**
Registration timing: **prospective**

Last update: **2026-09-24, 1405/07/02**
Update count: **0**

Registration date

2026-09-24, 1405/07/02

Registrant information

Name

Bahram Davoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-02, 1405/07/10

Expected recruitment end date

2027-04-30, 1406/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative Evaluation of Changes in Clinical Severity and Inflammatory Biomarkers in Hidradenitis Suppurativa Patients Receiving Infliximab With Versus Without Adjunctive Tirzepatide (Spartina) Therapy

Public title
The effect of adding Tirzepatide on severity of Hidradenitis Suppurativa in patients treated with Infliximab

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 to 65 years diagnosed with Hidradenitis Suppurativa (Hurley stage II or III) BMI >= 27 kg/m2 Receiving stable and continuous treatment with Infliximab for at least 12 weeks Written informed consent

Exclusion criteria:

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible patients will be randomly allocated into two equal groups (1:1 ratio) using simple randomization. The intervention group will receive Infliximab plus Tirzepatide, while the control group will continue Infliximab alone. This randomization aims to reduce bias and balance baseline characteristics.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of School of Medicine, Tehran University of Medical Sciences

Street address
School of Medicine, Poursina St., Enghelab Sq.

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2026-09-19, 1405/06/28

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1405.303

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
Hidradenitis Suppurativa Clinical Response (HiSCR)

Timepoint
At baseline (week 0), and weeks 8, 16, and 24 after the start of intervention

Method of measurement
Clinical examination by a dermatologist counting the number of inflammatory lesions (abscesses and nodules) and draining fistulas

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients receive subcutaneous injections of Tirzepatide (starting at 2.5 mg weekly and increasing to 7.5 mg over 8 weeks) in addition to their standard treatment with Infliximab

Category
Treatment - Drugs

2

Description
Control group: patients will continue their standard treatment with Infliximab only and will not receive any placebo or additional medication

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Dermatology Hospital

Full name of responsible person
Dr. Maryam Ghiasi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Vice-Chancellor for Research and Technology

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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
BAHRAM DAVOUDI

Position
Dermatology Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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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