Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A phase Ш, randomized, two-armed, double-blind, multicenter, parallel, active-controlled, non-inferiority clinical trial to compare efficacy and safety of guselkumab (CinnaGen co) versus Tremfya® (Janssen co) in patients with moderate to severe plaque psoriasis

Protocol summary

Study aim
Efficacy and safety of guselkumab CinnaGen co vs. Tremfya® in moderate to severe plaque psoriasis

Design
Phase III, randomized, two-armed (73 patients in each arm), double-blind, parallel, active-controlled, non-inferiority,

Settings and conduct
Eligible plaque psoriasis patients in Tehran/other mentioned centers, randomized, double-blind (patient, health-care provider and analyzer)

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18 to 75 year moderate-to-severe plaque psoriasis systemic treatment candidates, inadequate response to adalimumab, golimumab, infliximab, anakinra, or etanercept and discontinuing them for a specific period, informed consent form signing Exclusion criteria: History/symptoms of severe, progressive, or uncontrolled conditions, other autoimmune diseases, transplantation, nursing/pregnancy/planning it, nonplaque form of psoriasis, drug-induced psoriasis, major surgery/planning it/ not recovery, substance abuse, hypersensitivity to the formulation/latex, receiving protocol-prohibited treatments, recent receiving of investigational agent/participating in clinical studies, recent receiving/ expecting to receive live vaccinations, tuberculosis, hepatitis B/C or human immunodeficiency virus, abnormal laboratory tests according to the protocol, serious infection/hospitalization/recent receiving of injectable/oral antibiotics, recent herpes zoster, malignancy/ its history, other conditions making subject enrollment inappropriate.

Intervention groups
Intervention: Guselkumab, 100 mg, day 0 and weeks 4, 12, 20, 28, 36, and 44, subcutaneous injection Control: Tremfya®, 100 mg, day 0 and weeks 4, 12, 20, 28, 36, and 44, subcutaneous injection

Main outcome variables
Psoriasis Area Severity Index (PASI)

General information

Reason for update
Considering the minor changes in the protocol, including the removal of Dr. Robati from the list of study investigators, after approval from the Food and Drug Administration and the Ethics Committee, the changes have been applied to the system for updating purposes.

Acronym

IRCT registration information
IRCT registration number: **IRCT20150303021315N34**
Registration date: **2024-11-06, 1403/08/16**
Registration timing: **prospective**

Last update: **2025-08-03, 1404/05/12**
Update count: **1**

Registration date
2024-11-06, 1403/08/16

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2024-12-19, 1403/09/29
Expected recruitment end date
2027-12-20, 1406/09/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A phase Ш, randomized, two-armed, double-blind, multicenter, parallel, active-controlled, non-inferiority clinical trial to compare efficacy and safety of guselkumab (CinnaGen co) versus Tremfya® (Janssen co) in patients with moderate to severe plaque psoriasis

Public title
Evaluation of non-inferiority of efficacy and safety of guselkumab (CinnaGen co) versus Tremfya® (Janssen co)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male or female between 18 to 75 years of age (inclusive). Have a diagnosis of plaque-type psoriasis, with or without psoriatic arthritis, for at least 6 months before the first administration of the study intervention. Have an involved BSA (Body Surface Area) at least 10 percent at screening. Have a PASI (Psoriasis Area Severity Index) at least 12 at screening. Have an IGA (Investigator's Global Assessment) at least 3 at screening. Be a candidate for systemic treatment for plaque psoriasis Inadequate response in case of treatment with adalimumab, golimumab, infliximab, anakinra, or etanercept.(In this condition, these treatments should have been discontinued before specific durations prior to the first administration of the study intervention:- Adalimumab, golimumab, infliximab, or anakinra at least 4 weeks before the first administration of the study intervention.- Etanercept at least 2 weeks before the first administration of the study intervention). Ability to comprehend and willingness to sign the informed consent form for this study.
Exclusion criteria:
Has a history or current signs or symptoms of severe, progressive, or uncontrolled medical conditions due to the investigator’s opinion. Has other autoimmune diseases (e.g, inflammatory bowel disease, etc.) Has a transplanted organ (with the exception of a corneal transplant at least 3 months before the first administration of study intervention). Is pregnant, nursing, or planning a pregnancy (both men and women) while enrolled in this study and within 12 weeks following the last administration of the study intervention. Has a nonplaque form of psoriasis (e.g., erythrodermic, guttate, or pustular). Has current drug-induced psoriasis (e.g., a new onset of psoriasis or an exacerbation of psoriasis from beta blockers, calcium channel blockers, or lithium). Has had major surgery (e.g., requiring general anesthesia and hospitalization) within 8 weeks before screening, or will not be fully recovered from such surgery, or has such surgery planned during the time the subject is expected to participate in the study (52 weeks).(Note: Subjects with planned surgical procedures to be conducted under local anesthesia may participate.) Is known to have had a substance abuse (drug or alcohol) problem within the previous 12 months prior to screening due to investigator’s opinion. Has hypersensitivity, allergies, or known intolerance to the formulation, or known allergy or sensitivity to latex. Has previously received guselkumab. Has received any therapeutic agent directly targeted to IL-12, IL-17A, IL-17R, or IL-23 within 6 months prior to the first administration of study intervention (including but not limited to ustekinumab, tildrakizumab, risankizumab, ixekizumab, brodalumab, or secukinumab.)IL: Interleukin Has received natalizumab, belimumab, or agents that modulate B cells or T cells (e.g., rituximab, alemtuzumab, abatacept, or visilizumab) within 12 months prior to the first administration of study intervention. Has received any systemic immunosuppressants (e.g., methotrexate [MTX], azathioprine, cyclosporine, 6-thioguanine, mercaptopurine, mycophenolate mofetil, or JAK (Janus Kinase) inhibitors) within 4 weeks of the first administration of study intervention Has received phototherapy or any systemic medications/treatments (including, but not limited to, oral or injectable corticosteroids, retinoids, 1,25-dihydroxy vitamin D3 or analogues, psoralens, sulfasalazine, hydroxyurea, apremilast, fumaric acid derivatives) or any systemic or topical herbal treatments or traditional medicines that could affect psoriasis within 4 weeks of the first administration of study intervention. Is currently receiving lithium, antimalarials, or intramuscular (IM) gold, or has received lithium, antimalarials, or IM gold within 4 weeks of the first administration of the study intervention. Has received any investigational agent within 30 days or passing less than 5 half-lives of the investigational agent (whichever is longer) of the first administration of the study intervention or participating in clinical studies consisting of any investigational agent or procedure. Has received, or is expected to receive, any live virus or bacterial vaccination within 3 months before the first administration of the study intervention. Having hepatitis B, hepatitis C, or HIV (Human Immunodeficiency Virus) infection. Abnormal laboratory tests at the screening, including:- GFR (Glomerular Filtration Rate) less than 30 mL/min (Mililitter per Minute) (based on Cockcroft-Gault Equation)- Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) levels more than100 IU/L (International Units Per Liter)Note: Patients with hepatic enzymes (AST or ALT) of at least 70 IU/L up to maximum 100 IU/L at the screening, need a hepatologist's approval for the study enrollment.- Total bilirubin or alkaline phosphatase (ALP) at least 3 × ULN (Upper Limit of Normal)Note: Patients with total bilirubin or ALP greater or equal to 2 up to 3 × ULN at the screening, need a hepatologist's approval for the study enrollment.- Hemoglobin less than 8 g/dL

(Grams per Decilitre)- Platelet less than 100 × 103/µL (Microlitter)- Neutrophil less than 1.5 × 103/µL- WBC (White Blood Cells) less than 3.5 × 103/µL Tuberculosis (TB) assessment with PPD (Purified Protein Derivative) more than 5mm or positive IGRA (Interferon-Gamma Release Assay).Note: Patients who have received complete treatment for latent TB prior to enrolling the study can participate. Has or has had a serious infection or has been hospitalized or received injectable antibiotics for an infection within 8 weeks or oral antibiotics within 2 weeks prior to the first administration of the study intervention. Has or has had herpes zoster within 2 months before the screening. Currently has a known malignancy or has a history of malignancy. Having any other condition which, in the opinion of the investigator, will make the subject inappropriate for enrolling the study or that could prevent, limit, or confound the protocol-specified assessments.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **146**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of patients will be conducted using R-CRAN software version 4.2.2. The process involves creating random blocks that are stratified based on two variables: the history of previous biologic failure (yes/no) JAK inhibitors failure (yes/no). Blocks of sizes 2 and 4 will be used for a total of 146 patients, maintaining a ratio of 1:1. For each combination of these variables, a random list containing various combinations of 2 or 4 blocks will be generated, and the randomization process will occur centrally. Each patient will be assigned to one of these combinations upon entering the study. Once assigned, the patient will contact the unit responsible for randomization, which will use the relevant random list to allocate them to a specific drug group.After randomization is complete, each patient will receive a unique identification code for the duration of the study. This code will consist of 4 letters (the first two letters of the first name followed by the first two letters of the last name), three numbers representing the center code, three letters corresponding to the generic drug name (GSK), and three digits for the randomization code. For example, a patient code could look like ABCD001GSK-001. Randomization numbers will be assigned sequentially.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both guselkumab drugs under study were unrecognizable to patients and the relevant medical staff because they are completely similar in terms of shape, size, gender, and color, and it is not possible to distinguish the brand of drugs from their appearance. The drug container of both guselkumab drugs is placed in the same type of packaging, so that they are not distinguishable in appearance. The group of patients and the type of medicine they received will not be disclosed to the researchers. After ensuring the eligibility of the patient and signing the informed consent form, according to the main randomization sheet of the trial, the patients are placed in a specific treatment group. (The original trial randomization sheet remains in the CRO of the trial, and after checking the eligibility criteria, the randomization code is announced to the prescriber by phone call.) The randomization will not be disclosed to the study administrators and is located in the coded envelopes with the trial CRO representative. The people who review the results and analyze the data are not aware of the type of patient grouping.

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 Science

Street address

604, 6th floor, Centeral building of Tehran University of Medical Science, Qods and Keshavarz st

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Province

Tehran

Postal code

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Approval date

2024-10-19, 1403/07/28

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.347

Health conditions studied

1

Description of health condition studied

Plaque Psoriasis

ICD-10 code

L40.0

ICD-10 code description

Psoriasis vulgaris

Primary outcomes

1

Description

Response to treatment based on proportion of patients with PASI 75 at week 16- PASI: Psoriasis Area Severity Index - PASI 75 means at least 75% decrease in the PASI score of the patient compared to the screening visit

Timepoint

Screening, week 16

Method of measurement

Physician assessment based on PASI questionnaire

Secondary outcomes

1

Description

Response to treatment based on proportion of patients with PASI 100 at weeks 16 and 52- PASI 100 means a 100% decrease in the PASI score of the patient compared to the screening visit and complete recovery.

Timepoint

Screening, week 16, week 52

Method of measurement

Physician assessment based on PASI questionnaire

2

Description

Response to treatment based on proportion of patients with PASI 90 at weeks 16 and 52- PASI 90 means at least 90% decrease in the PASI score of the patient compared to the screening

Timepoint

Screening, week 16, week 52

Method of measurement

Physician assessment based on PASI questionnaire

3

Description

Response to treatment based on proportion of patients with PASI 75 at week 52

Timepoint

Screening, week 52

Method of measurement

Physician assessment based on PASI questionnaire

4

Description

Response to treatment based on proportion of patients with IGA scores of 0 or 1 at weeks 16 and 52- IGA: Investigator's Global Assessment - IGA scores of 0 or 1 mean clear or almost clear of signs of psoriasis

Timepoint

Screening, week 16, week 52

Method of measurement

Physician assessment based on IGA questionnaire

5

Description

Evaluation of patients quality of life- The evaluation of patients quality of life is based on the Dermatology Life Quality Index (DLQI) questionnaire that evaluates the impact of skin conditions on quality of life from patients' point of view.

Timepoint

Screening, week 52

Method of measurement

DLQI questionnaire

6

Description

The severity of nails involvements- The severity of nails involvements is based on NAPSI (Nail Psoriasis Severity Index) score that evaluates severity and level of psoriasis affected nails. Each nail can have a 0-8 score.

Timepoint

Screening, week 16, week 52

Method of measurement

Physician assessment based on NAPSI questionnaire

Intervention groups

1

Description

Intervention group: Guselkumab (CinnaGen co.) 100 mg/mL, 100 mg in each pre-filled syringe (PFS), at day 0 and weeks 4, 12, 20, 28, 36, and 44 for subcutaneous injection in the lower abdomen, arms or thighs.

Category

Treatment - Drugs

2

Description

Control group: Tremfya® (Janssen co.) 100 mg/mL, 100 mg in each pre-filled syringe (PFS) at day 0 and weeks 4, 12, 20, 28, 36, and 44 for subcutaneous injection in the lower abdomen, arms or thighs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr Balighi Dr Danesh Pajooh Dr Lajevardi Dr Mahmoodi Dr Azizpoor Dr Safarian Dr Ghandi

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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3

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4

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5

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6

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Name of recruitment center
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Sponsors / Funding sources

1

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Email
cinnagen@cinnagen.com
Web page address
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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
Cinnagen company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
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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
Not applicable

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
Not applicable