Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of infliximab on lean body mass and body mass index in psoriasis patients

Protocol summary

Summary

One of the drug treatments for psoriasis is anti TNF-a treatment.TNF particularly the alpha subtype is a cytokine which is produced by immune system in inflammatory disorders.This drug can lead to increase in leptin and therefore lead to increase in BMI(body mass index). This issue may affect the results of the treatment, since weight increase leads to increase in severity of psoriasis. The inclusion criteria consisted of psoriatic patients candidate for treatment with anti TNFa inhibitors and no contradiction for infliximab treatment, exclusion criteria consisted of pregnant women; breastfeeding women and concomitant use of systemic retinoid. This study is a clinical trial of before-after type studies.The sample of study are psoriatic patients who are candidates for receiving infliximab infusion. the sample size is 22. The infusion will be performed intravenously in 5mg/kg dose, at the beginning of the study and after 2,6 and 8 weeks and after that every 8 week until week twenty-four.In each infusion height, weight, BMI, LBM and severity of the disease based on PASI score will be measured and levels of cholesterol and triglyceride and leptin will be measured at the beginning and the end of the treatment.the effect of the treatment on these variables will be assessed,to evaluate weather increase in BMI with this drug leads to poor outcome in this therapy or not.

General information

Acronym

BMI,LBM

IRCT registration information

IRCT registration number: **IRCT2013082912065N1**
Registration date: **2013-08-29, 1392/06/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-29, 1392/06/07

Registrant information

Name
Arghavan Azizpour
Name of organization / entity
Razi Hospital
Country
Iran (Islamic Republic of)
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+98 21 5563 0668
Email address
a-azizpour@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science, Razi Hospital

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of infliximab on lean body mass and body mass index in psoriasis patients

Public title

The effect of infliximab on precentage of body fat and weight in psoriasis patients

Purpose

Health service research

Inclusion/Exclusion criteria

inclusion criteria : patients with psoriasis; candidate for treatment with infliximab; having consent from the patient to participate in the study; no contradiction for infliximab treatment exclusion criteria : not being able to follow up the patient; pregnant women; breastfeeding women; concomitant use of other cytotoxic drugs; Severe complications leading to treatment discontinuation; concomitant use of systemic retinoid

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethic committee of Tehran University of Medical Sciences

Street address
Ghods avenue,

City
Tehran

Postal code

Approval date
2012-11-08, 1391/08/18

Ethics committee reference number
91/130/1923/د

Health conditions studied

1

Description of health condition studied
psoriasis

ICD-10 code
L40

ICD-10 code description
psoriasis

Primary outcomes

1

Description
body mass index

Timepoint
before initiation of the study,week 6,12, and 24 after the last dose

Method of measurement
weight with kilograms on a scale,height with meters with the use of a rubber meter

2

Description
lean body mass

Timepoint
before initiation of the study,week 6,12, and 24 after the last dose

Method of measurement
weight with kilograms on a scale,height with meters with the use of a rubber meter

Secondary outcomes

1

Description
leptin

Timepoint
before initiation and after the last dose

Method of measurement
lab

2

Description
cholestrol

Timepoint
before initiation and after the last dose

Method of measurement
lab

3

Description
trigliseride

Timepoint
before initiation and after the last dose

Method of measurement
lab

Intervention groups

1

Description
g infliximab infusion.the infusion will be performed intravenously in 5mg/kg dose, at the beginning of the

study and after 2,6 and 8 weeks and after that every 8 week until week twenty-four

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Arghavan Azizppour

Street address

Vahdateslami avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science,Razi Hospital

Full name of responsible person

Dr AmirHoushang Ehsani

Street address

Vahdateslami avenue

City

Tehran

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 Science,Razi Hospital

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

Razi hospital

Full name of responsible person

Arghavan Azizpour

Position

resident

Other areas of specialty/work

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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