

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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- α 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 TNF α 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 whether 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)

Phone

+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 percentage 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

91/130/1923/3

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

cholesterol

Timepoint

before initiation and after the last dose

Method of measurement

lab

3

Description

triglyceride

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 Azizpour

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

Street address

Vahdateslami avenue

City

Tehran

Postal code

Phone

+98 21 5563 0668

Fax

Email

www.tums.ac.ir/raz

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Razi hospital

Full name of responsible person

Arghavan Azizpour

Position

resident

Other areas of specialty/work

Street address

Vahdateslami avenue

City

Tehran

Postal code

Phone

+98 21 5563 0668

Fax

Email

a63a@yahoo.com a-azizpour@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Razi hospital

Full name of responsible person

Arghavan Azizpour

Position

resident

Other areas of specialty/work

Street address

Vahdateslami avenue

City

Tehran

Postal code

Phone

+98 21 5563 0668

Fax

Email

a63a@yahoo.com a-azizpour@razi.tums.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