

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of Tofacitinib in maintenance therapy of patients with ulcerative colitis

Protocol summary

Study aim

The main aim of this study is to assess the efficacy of Tofacitinib in moderate to severe Ulcerative Colitis patients

Design

One arm, non blinded, clinical trial 40 ulcerative colitis patients who have respond to induction therapy to Tofacitinib, ill be enrolled for continuation of therapy. these patients will recieve Tofacitinib (10 mg/ day) for another 10 months and clinical response to maintenance therapy to Tofacitinib will be assessed in these patients

Settings and conduct

This clinical trial is consisted of only one intervention group. The patients will be drawn from a list of Ulcerative Colitis patients referring to Gastrointestinal out patient clinic of Shariati hospital affiliated with Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age> 18 years old Known case of Ulcerative Colitis Mayo score ≥ 6 in last 4 months No clinical response or clinical remission (failed treatment) after anti TNF being used for at least 12- 14 weeks or Azathiopurin used for at least 8-10 weeks Unacceptable side effects after Corticostroid, Azathioprine, Mercaptopurine, Infliximab, or Adalimumab therapy Being enrolled in phase 1 of study (induction therapy with Tofacitinib) Clinical response to induction therapy (2 months treatment duration) with Tofacitinib

Intervention groups

There is one intervention group in this study which would be selected based on inclusion and exclusion criteria. The included patients will orally receive 2 tablets of Tofacitinib (10mg/ day) for 10 months.

Main outcome variables

Mayo score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181217042020N2**

Registration date: **2019-03-12, 1397/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-12, 1397/12/21**

Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

Ali Reza Sima

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8241 5238

Email address

a-sima@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Tofacitinib in maintenance therapy of patients with ulcerative colitis

Public title

Effects of Tofacitinib on Ulcerative Colitis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age > 18 years old Known case of Ulcerative Colitis Mayo score ≥ 6 in last 4 months No clinical response or clinical remission (failed treatment) after ant TNF being used for at least 12- 14 weeks or Azathiopurin used for at least 8-10 weeks Unacceptable side effects after Corticostroid, Azathioprine, Mercaptopurine, Infliximab, or Adalimumab therapy Being enrolled in phase 1 of study (induction therapy with Tofacitinib) Clinical response to induction therapy (2 months treatment duration) with Tofacitinib

Exclusion criteria:

Abnormal chest x ray pregnant women or women who plan to become pregnant Acute infection GFR < 60 ml/min Known case of cancer positive TB test (PPD/ or IGRA test) Being positive for tests: HBV, HCV, HIV, CMV

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

This study is designed as the second phase of study entitled " Evaluation of Tofacitinib efficacy for induction therapy in patients with Ulcerative Colitis ". In that study, 50 patients aged 18 years and older who had moderate-to severe Ulcerative Colitis and didnot clinically respond to conventional therapy (didnot enter in clinical response or clinical remission phase) will recieve 20 mg / day Tofacitinib (Fanavaran Rojan Mohaghegh darou Co.) for 2 months. Patients who clinically respond to Tofacitinib (assessed by biochemical and clinical assessment) will enter into second phase which is the present study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Digestive Disease Research
Institute of Tehran University of Medical Sciences

Street address

Digestive Disease Research Institute, Shariati
hospital, North Kargar street,

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.TUMS.DDRI.REC.1397.016

Health conditions studied**1****Description of health condition studied**

Ulcerative Colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes**1****Description**

Mayo score

Timepoint

At the beginning, 3 months and 9 months after entering
this phase of study

Method of measurement

Colonoscopy

Secondary outcomes**1****Description**

Lipid profile

Timepoint

At the beginning, 3 months and 9 months after entering
this phase of study

Method of measurement

Enzymatic method

2**Description**

Liver function test

Timepoint

At the beginning, 3 months and 9 months after entering
this phase of study

Method of measurement

Autoanalyser

3

Description

ESR

Timepoint

At the beginning, 3 months and 9 months after entering this phase of study

Method of measurement

Autoanalyser

Intervention groups

1

Description

Intervention group: Medication: Tofacitinib 5 mg; Dose: 10 mg/day (2 tablets); frequency: 2 times per day (1 tablet in the morning; 1 tablet in the evening); Duration: 10 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Digestive Disease Research Institute

Full name of responsible person

Dr. Homayoun Vahedi

Street address

Digestive Disease Research Institute, Shariati hospital, North Kargar street,

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8241 5000

Email

info@ddri.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Digestive Disease Research Institute of Tehran University of Medical Sciences

Full name of responsible person

Dr. Reza Malekzadeh

Street address

Digestive Disease Research Institute, Shariati hospital, North Kargar street

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8241 5000

Fax

+98 21 8241 5400

Email

info@ddri.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Digestive Disease Research Institute of 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

Digestive Disease Research Institute

Full name of responsible person

Sudabeh Alatab

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Digestive Disease Research Institute, Shariati hospital, North Kargar street,

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8241 5000

Fax

+98 21 8241 5400

Email

sudabehalatab@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Digestive Disease Research Institute of Tehran
University of Medical Sciences

Full name of responsible person

Dr. Homayoun Vahedi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterologist

Street address

Digestive Disease Research Institute, Shariati
hospital, North Kargar street,

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8241 5000

Email

homayoonvahedi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Digestive Disease Research Institute of Tehran
University of Medical Sciences

Full name of responsible person

Sudabeh Alatab

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Digestive Disease Research Institute, Shariati
hospital, North Kargar street,

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8241 5000

Email

sudabehalatab@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Data of participants: at the end of study and after
publication of results, the file of the primary and
secondary outcomes as well as demographic and past
medical history of participants could be shared. the
consent form: the approved consent form could be
shared

When the data will become available and for how long

Start date of sharing: Three months after publication of
results End date of sharing: Nine months after
publication of results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

In case academic researchers are interested in obtaining
these data, they should contact (by official academic
email) the scientific responsible of this study and ask for
data. the data can not be used for publishing the paper

From where data/document is obtainable

For requesting the data, the academic researcher
should contact by academic email the scientific
responsible of the study Dr. Homayoun Vahedi
dr_vahedi@yahoo.com

What processes are involved for a request to access data/document

The reason for requesting the data and type of use
should be mentioned in request. if the conditions are
satisfactory for the scientific responsible of study and
other collaborators of the study, then the requested data
will be shared. This process might take up to one month.

Comments