

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Evaluation of Tofacitinib efficacy for induction therapy in 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 consisted of 50 Ulcerative colitis 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 1- Age > 18 years old; 2- Known case of Ulcerative Colitis; 3- Mayo score ≥ 6 in last 4 months; 4- Rectal bleeding subscore of 1 to 3 in last 4 months; 5- Endoscopic subscore of 2 or 3 in last 4 months; 6- No clinical response or clinical remission (failed treatment) after anti- TNF drugs being used for at least 12- 14 weeks or Corticostroid and Azathiopurin used for at least 8-10 weeks; 7- Unacceptable side effects after Corticostroid, Azathioprine, Mercaptopurine, Infliximab, or Adalimumab therapy. Exclusion criteria 1- Abnormal chest x ray; 2- pregnant women or women who plan to become pregnant; 3- Acute infection; 4- GFR < 60 ml/min; 5- Known case of cancer; 6- positive TB test (PPD/ or IGRA test); 7- Being positive for tests: HBV, HCV, HIV, CMV.

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 4 tablets of Tofacitinib (20 mg) per day for 2 months.

Main outcome variables

Mayo score that is based on colonoscopy findings, clinical symptoms and physician perception of patients well being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181217042020N1**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

Registration date

2019-02-10, 1397/11/21

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

2018-12-22, 1397/10/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Tofacitinib efficacy for induction therapy in patients with Ulcerative Colitis

Public title

Tofacitinib therapy in 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 Rectal bleeding subscore of 1 to 3 in last 4 months Endoscopic subscore of 2 or 3 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

Exclusion criteria:

1- 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: **50**

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 the first study for evaluation of effectiveness of Tofacitinib (as a JAK inhibitor agent) in our country. Despite the availability of this drug in other countries, Tofacitinib has not been yet available for Ulcerative Colitis patients in our country. Implementation of this study could facilitate the introduction of this drug to our permitted list of medications and smooth the way for performing the phase III and IV of clinical trials for this intervention.

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

North Kargar street, Shariati Hospital, Digestive Disease Research Institute

City

Tehran

Province

Tehran

Postal code

۱۴۱۱۷۱۳۱۳۵

Approval date

2018-11-03, 1397/08/12

Ethics committee reference number

IR.TUMS.DDRI.REC.1397.015

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 of enrollment and 2 months after start of intervention

Method of measurement

Colonoscopy

Secondary outcomes

1

Description

Lipid profile

Timepoint

At baseline and 2 months after intervention

Method of measurement

Enzymatic method

2

Description

Liver function test

Timepoint

At baseline and 2 months after intervention

Method of measurement

Autoanalyser

3

Description

ESR

Timepoint

At baseline and 2 months after intervention

Method of measurement

Autoanalyser

Intervention groups

1

Description

Intervention group: Medication: Tofacitinib 5 mg; Dose: 20 mg/day (4 tablets); frequency: 2 times per day (2 tablets in the morning; two tablets in the evening); Duration: 2 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

North Kargar street, Shariati hospital, Digestive Disease Research Institute

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Digestive Disease Research Institute of Tehran University of Medical Sciences

Full name of responsible person

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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

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 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

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

Associate professor

Latest degree

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Other areas of specialty/work

Gastroenterologist

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Position

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Latest degree

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Other areas of specialty/work

Medical Genetics

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Email

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

No - There is not 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, thee 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