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 Azathioporin 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 colonoscoy 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
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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 Azathioporin 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
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North Kargar street, Shariati hospital, Digestive Disease Research Institute
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 Diseaase Research Institute of Tehran University of Medical Sciences
Full name of responsible person
Sudabeh Alatab
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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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