

A comparative study on how well upadacitinib performs compared to oral prednisolone in treating and sustaining remission in moderate to severe ulcerative colitis

Submission date 02/03/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/03/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/07/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The purpose of this study is to investigate and compare the effectiveness and safety of two different treatment options (Upadacitinib vs Prednisolone) which are currently available for the induction and maintenance of remission in patients with moderate-to-severe ulcerative colitis (UC).

Who can participate?

The sample population will include all patients between the ages of 18 – 60 years with moderate-to-severe UC.

What does the study involve?

The study consists of two phases: an induction trial lasting 8 weeks, followed by a maintenance trial lasting 40 weeks, totaling 48 weeks.

During the induction trial, participants will either receive Upadacitinib at a daily dose of 45mg or oral Prednisolone at a daily dose of 40mg, which will then be tapered by 5mg each week. If a good response is observed by week 8, participants will continue or switch to Upadacitinib for the maintenance trial, lasting an additional 40 weeks. The maintenance dose depends on prior exposure to biologic therapy: biologic-naïve participants will receive Upadacitinib 15mg daily, while those previously exposed to biologic therapy will receive Upadacitinib 30mg daily.

Participants not showing a clinical response by week 8 will be withdrawn from the study and offered alternative treatment options. Although treatments are randomly assigned, both participants and researchers will be aware of the assigned treatment, and participants will receive an information sheet detailing their treatment.

Before treatment, participants will undergo blood tests for Hepatitis B, Hepatitis C, TB, and HIV. Positive results will lead to withdrawal from the study. Eligible participants will undergo baseline

colonoscopy and repeat colonoscopy at weeks 8 and 48. Stool and blood samples will be collected at weeks 0, 8, and 48 for testing. Participants will keep a symptom diary and complete questionnaires to assess the impact of ulcerative colitis on their quality of life.

During the induction trial, participants will attend the IBD clinic at weeks 2, 4, and 8. If eligible for the maintenance trial, clinic visits will occur every 8 weeks until week 48, allowing for reporting of adverse events and monitoring of drug levels.

What are the possible benefits and risks of participating?

The main benefit will be that derived directly from receiving one of the treatment options offered by the study. The treatment is expected to lead to an overall improvement in your symptoms and thus, overall improvement in your health-related quality of life.

Furthermore, other indirect benefits will involve those derived from utilizing the results of this study to contribute to the scientific knowledge that is known about the efficacy and safety of the treatment options that are currently available for ulcerative colitis.

The physical risks may include those related to the side effects of your allocated treatment. More specific details about each treatment will be provided to you once the random assignment of treatment is complete. Other risks may include the risks of undergoing a colonoscopy which include the risk of bleeding, infection, perforation, abdominal pain, and reaction to the sedative given during the procedure. Moreover, you may experience some mild discomfort when getting your blood drawn for the laboratory tests mentioned above. You may develop some bruising and minor tenderness around the site of needle insertion.

Where is the study run from?

Ministry of Health Kuwait

When is the study starting and how long is it expected to run for?

February 2024 to June 2026

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Mohammad Shehab, dr_mshehab@hotmail.com

Contact information

Type(s)

Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Study information

Scientific Title

Comparative efficacy and safety of upadacitinib versus oral prednisolone for the induction and maintenance of remission in moderate to severe ulcerative colitis: a prospective, multicenter, open-label, randomised controlled trial (PREDUPA Trial)

Acronym

PREDUPA

Study objectives

Upadacitinib is more efficacious and safe than oral prednisolone at inducing and maintaining remission in moderate-to-severe ulcerative colitis.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 22/07/2024, Permanent Committee for Coordination and Health Research - Ministry of Health Kuwait (Sulaibkhat - Jamal Abdel Nasser Street, Kuwait City, PO Box 5, Zip code 13001, Kuwait; +965 1810005; appsupport@moh.gov.kw), ref: 1217

Study design

Prospective multicenter open-label randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Safety, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Moderate-to-severe ulcerative colitis

Interventions

This study will be a prospective, multicenter, open-label, randomised controlled trial in Kuwait. It is comprised of an 8-week induction trial followed by a 40-week maintenance trial with a treat-through design. The sample population will include all patients between the ages of 18 – 60 with

moderate-to-severe UC. To be enrolled, patients must have a Modified Mayo Score (MMS; range 0 – 9, with higher scores being indicative of greater severity of UC) between 4 – 9 with an endoscopic subscore of 2 – 3 at baseline (week 0). The endoscopic subscores will be based on images or videos taken during colonoscopies done by consultant gastroenterologists or endoscopists at multiple centres across Kuwait. The endoscopic Mayo scores will be validated by a single IBD specialist who will then be blinded to treatment allocation, clinical response and endoscopy time point throughout the whole 48-week study period.

Eligible patients will then be randomly assigned in a 1:1 ratio to receive either Upadacitinib (45mg daily) or oral Prednisolone (40mg daily, tapered by 5mg every week) for a total duration of 8 weeks. Participants who achieve clinical response at week 8 will proceed into the maintenance trial whereby all responders will either continue or commence treatment with Upadacitinib at a maintenance dose for 40 additional weeks (15mg once daily and 30mg once daily for biologic-naïve and biologic-experienced patients, respectively).

Intervention Type

Drug

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Upadacitinib, prednisolone

Primary outcome measure

Primary outcomes for the induction trial (week 1 – 8):

1. Clinical response or clinical remission at week 8:

1.1. Clinical response – defined as a decrease in the MMS by ≥ 2 points with an overall decrease of $\geq 30\%$ from baseline, in addition to either a rectal bleeding (RB) subscore of 0 or 1 or a decrease in RB subscore by ≥ 1 point from baseline.

1.2. Clinical remission – defined as a modified Mayo stool-frequency (SF) subscore of 0 or a SF subscore of 1 with a decrease of ≥ 1 point from baseline, in addition to a RB subscore of 0 and an endoscopic subscore (ES) of 0 or 1.

Primary outcomes for the maintenance trial (week 9 – 48):

2. Clinical remission at week 40 (i.e. at 48 weeks overall)

2.1. Clinical remission – defined as a modified Mayo stool-frequency (SF) subscore of 0 or a SF subscore of 1 with a decrease of ≥ 1 point from baseline, in addition to a RB subscore of 0 and an endoscopic subscore (ES) of 0 or 1.

Secondary outcome measures

1. Inflammatory bowel disease questionnaire (IBD-Q) score to assess health-related quality of life: This will be assessed at baseline (week 0) then repeated at week 8 and 48 of the study.

2. C-Reactive Protein (CRP) (<10): A blood sample will be taken to monitor the CRP level at baseline (week 0), week 8 and 48 of the study.

3. Fecal calprotectin (<200): A fecal sample will be collected to monitor the fecal calprotectin level at baseline (week 0), week 8 and 48 of the study.

Overall study start date

01/02/2024

Completion date

01/06/2026

Eligibility

Key inclusion criteria

1. Males + Females with moderate-to-severe UC
2. Age 18 – 60 years
3. All durations of disease
4. All extents of disease (proctitis / left-sided colitis / pancolitis)
5. Previously failed to respond to conventional therapies and/or anti-TNF therapy
6. Biologic-naïve
7. On a stable dose of 5-ASA or immunomodulator four weeks prior to the start of the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Pregnant / lactating
2. Crohn's colitis
3. Latent or active TB
4. Active infection
5. Current or past malignancy
6. Active or past thromboembolic disease

Date of first enrolment

01/09/2024

Date of final enrolment

01/09/2025

Locations

Countries of recruitment

Kuwait

Study participating centre**Mubarak Al-Kabeer Hospital**

Jabriya, Block 4, Street 109

Kuwait City

Kuwait

046304

Study participating centre**Farwaniya Hospital**

Block 6, Sabah Al Nasser street.

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PO Box 13373 Farwaniya 81004

Study participating centre**Sheikh Jaber Al-Ahmad Al-Sabah Hospital**

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Sponsor information**Organisation**

Ministry of Health Kuwait

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Sponsor type

Government

Website

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

25/03/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication