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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	[X] Prospectively registered [_] Protocol
Registration date 13/03/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 09/11/2026	**Condition category** Digestive System	[_] Individual participant data [X] 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Participants not showing a clinical response by week 8 will be withdrawn from the study and offered alternative treatment options.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 December 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mohammad Shehab, mohammad.shehab@aasu.edu.kw

Contact information

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Scientific, Principal investigator

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Additional identifiers

Protocol serial number
5262

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

Primary study design
Interventional

Study design
Prospective multicenter open-label randomized controlled trial

Study type(s)
Efficacy, Safety

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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Upadacitinib, prednisolone

Primary outcome(s)
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 ≥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.

Key secondary outcome(s)
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.

Completion date
01/12/2026

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
0

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
01/12/2026

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.
Kuwait City
Kuwait
PO Box 13373 Farwaniya 81004

Study participating centre
Sheikh Jaber Al-Ahmad Al-Sabah Hospital
Ministries Area - Block 1, Khalid Ben AbdulAziz Street.
Kuwait City
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PO Box 240 Safat, Code 13003

Study participating centre
Al-Sabah Hospital
Shuwaikh Medical Area (Al Sabah Health Region), Jamal Abdul Nasser Street
Shuwaikh Industrial
Kuwait City
Kuwait
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Sponsor information

Organisation
Abdullah Al-Salem University

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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