# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## A Post-Marketing Surveillance Study to Evaluate the Safety and Effectiveness of Upadacitinib (Nupada® produced by NanoAlvand Co.) in pa-tients with inflammatory bowel diseases.

## Protocol summary


**Study aim**

To evaluate the safety profile of Nupada® in real-world practice.

**Design**

Phase IV, Prospective, observational

**Settings and conduct**

This study will be conducted on 161 patients with inflammatory bowel disease (ulcerative colitis and Crohn's disease) who are candidates for treatment with Nupada® over 24 weeks. During this period, patients with ulcerative colitis will have 5 visits (at baseline, week 4, week8, week 16, and week 24), and patients with Crohn's disease will have 4 visits (at baseline, week 4, week 12, and week 24(. At each visit, participants will be evaluated and asked about the occurrence of adverse events after starting Nupada® by their physicians. Also, at each visit, the effectiveness of Nupada® will be evaluated with the partial Mayo score in patients with ulcerative colitis and with Harvey-Bradshaw index in patients with Crohn's disease. Furthermore, the effectiveness of Nupada® will be assessed by the percentage of pa-tients achieving clinical response at week 24 based on the Mayo score in patients with ulcerative colitis and the Harvey-Bradshaw index in patients with Crohn's disease.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria 1. Patients with ulcerative colitis or Crohn's disease 2. Patients who are candidates to receive Upadacitinib treatment according to the in-vestigator's opinion 3. Ability to comprehend and willingness to give consent for this study Exclusion criteria NA

**Intervention groups**

Tablets of Nupada® will be prescribed and ingested by patients with a dose and frequency based on the physician's opinion.

**Main outcome variables**

Adverse events occurred during study until week 24 based on the physician's assessment. Clinical re-sponse at week 24 based on changes in Mayo score in patients with ulcerative colitis and Harvey-Bradshaw in patients with Crohn's disease com-pared to baseline.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20150303021315N46**
Registration date: **2026-10-09, 1405/07/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-09, 1405/07/17**
Update count: **0**

**Registration date**

2026-10-09, 1405/07/17

**Registrant information**


**Name**

Nassim Anjidani

**Name of organization / entity**

Orchid Pharmed

**Country**

Iran (Islamic Republic of)

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+98 21 4347 3000

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amini@orchidpharmed.com


**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-10-02, 1405/07/10

**Expected recruitment end date**

2027-07-01, 1406/04/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Post-Marketing Surveillance Study to Evaluate the Safety and Effectiveness of Upadacitinib (Nupada® produced by NanoAlvand Co.) in pa-tients with inflammatory bowel diseases.

**Public title**

Study to evaluate safety and effectiveness of Upadacitinib (Nupada® produced by NanoAlvand Co.) in patients with inflammatory bowel diseas-es.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with ulcerative colitis or Crohn’s disease Patients who are candidates to receive Upadacitinib treatment according to the investigator’s opinion Ability to comprehend and willingness to give con-sent for this study

**Exclusion criteria:**

NA

**Age**

From **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **202**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

6th Floor, Building No. 2, University Headquarters, Shahid Beheshti University of Medical Sciences and Health Services, Arabi St., Chamran Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1546815514

**Approval date**

2026-07-25, 1405/05/03

**Ethics committee reference number**

IR.SBMU.RIGLD.REC.1405.007

## Health conditions studied

### 1

**Description of health condition studied**

Ulcerative colitis, Crohn’s disease

**ICD-10 code**

K51, K50

**ICD-10 code description**

Ulcerative colitis, Crohn's disease [regional enteri-tis]

## Primary outcomes

### 1

**Description**

To evaluate the safety of Upadacitinib (Nupada®, produced by NanoAlvand Co.) through the adverse events occurred during study based on physician assessment.

**Timepoint**

In every visit until week 24

**Method of measurement**

Adverse events occurred during the study based on physician assessment

## Secondary outcomes

### 1

**Description**

Percentage of patients with clinical response* at week 24*Definition of Clinical Response based on Mayo Score in patients with ulcerative colitis: A decrease of at least three points in the patient's Mayo Score compared to the screening visit,ANDA decrease of at least 30% in the patient's Mayo Score compared to the screening visit,ANDThe Subscore related to Rectal Bleeding must de-crease by at least one point, or the score for this cri-terion must be 0 or 1.*Definition of Clinical Response based on Harvey-Bradshaw Index in patients with Crohn’s disease: A decrease of at least three points in the patient's Har-vey-Bradshaw Index compared to the screening vis-it.

**Timepoint**
Mayo score in patients with ulcerative colitis: Baseline, Week 4, Week 8, Week 16, Week 24Harvey-Bradshaw index in patients with Crohn's disease:Baseline, Week 4, Week 12, Week 24
**Method of measurement**
Mayo score (for ulcerative colitis): Physician's assessment and colonoscopyHarvey-Bradshaw index (for Crohn's disease): Phy-sician's assessment

## Intervention groups

**1**

**Description**
Intervention group: Tablets of Nupada® (Upadacitinib produced by NanoAlvand Co.) will be prescribed and ingested by patients with a dose and frequency based on the physician's opinion
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Taleghani Hospital
**Full name of responsible person**
Dr. Shabnam Shahrokh
**Street address**
Gastroenterology and Liver Diseases Research Center, Talaghani Hospital Courtyard, Arabi St., Yemen St., Chamran Highway, Tehran, Iran
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Tehran
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Shabnamshahrokh@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
NanoAlvand Co.
**Full name of responsible person**
Dr.nima sepehri
**Street address**
Unit 52, 5th Floor, Owj Tower, No. 485, between 63rd and 65th Streets, Asadabadi St., Yousef Abad, Tehran, Iran
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**Province**
Tehran
**Postal code**
1434964744
**Phone**
+98 21 9107 7339
**Email**
info@nanoalvand.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
NanoAlvand Co.
**Proportion provided by this source**
30
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Industry

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Zist Orchid Pharmed Co
**Full name of responsible person**
Dr. Hamidreza Kafi
**Position**
Medical Department Manager
**Latest degree**
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**Other areas of specialty/work**
Medical Pharmacy
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## Person responsible for scientific inquiries

**Contact**
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Associate Professor
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## Person responsible for updating data

**Contact**
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**Position**
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Medical Pharmacy
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1994766411
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+98 21 4347 3000
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Kafi.H@orchidpharmed.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Not applicable