

# A study of the safety and efficacy of "Eryxin" in patients with rheumatoid arthritis

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| <b>Submission date</b><br>02/02/2024   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|  |   | <input checked="" type="checkbox"/> Protocol         |
| <b>Registration date</b><br>07/02/2024 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>14/04/2025       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

### Background and study aims

Rheumatoid arthritis is characterised by joint inflammation and destruction and leads to functional limitations, working disability, and a poor quality of life. It has an estimated adult prevalence of 0.8% worldwide and is more common in females. Synovial inflammation can cause erosive changes that are generally irreversible and often occur early in the disease process. Eryxin is a new drug with immunomodulatory and anti-inflammatory properties. The main goal of the study is to determine the safety of Eryxin and its efficacy in patients with rheumatoid arthritis

### Who can participate?

Adults age 18 years old and over with rheumatoid arthritis

### What does the study involve?

Participants will be asked to join this study while they are at a Clinic of Tashkent Medical Academy. The study will include the following periods:

- Screening - pre-screening of patients and initiation of therapy - randomization of patients, initiation of study therapy. The duration of the period should not be more than 24 hours.
- Therapy period (total duration of 30 days), application of study drug and/or traditional therapy, patient assessment, registration of AE.

### What are the possible benefits and risks of participating?

Possible benefits for participants include reducing pain and improving the quality of life. However, there may be adverse effects, which are the main risk for participants.

### Where is the study run from?

The study is being run by the Clinic of Tashkent Medical Academy and takes place in the Clinic of Tashkent Medical Academy.

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

September 2023 to April 2025

Who is funding the study?  
Namangan Pharm Plant LTD

Who is the main contact?  
Mr. Umid Akbarov, akbarov.umid@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Mr Umid Akbarov

### Contact details

Akkurgan str. 6 passage, 84b  
Tashkent  
Uzbekistan  
100052  
+998903219229  
akbarov.umid@gmail.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

ЭРИН36/350С/30Уз/2023/1876

## Study information

### Scientific Title

An open controlled non-randomized clinical trial to study the clinical efficacy of the drug "Eryxin" produced by "Namangan Pharm Plant"

### Study objectives

Is "Eryxin" safe and effective for the treatment of rheumatoid arthritis

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 09/11/2023, Ethics Committee of the Ministry of Health of the Republic of Uzbekistan (Oybek street, 45, Tashkent, 100015, Uzbekistan; +998712563738; info@minzdrav.uz), ref: 7-5/1806

## Study design

Interventional single-center open-label non-randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Safety, Efficacy

## Health condition(s) or problem(s) studied

Safety and efficacy in patients with rheumatoid arthritis

## Interventions

Current interventions as of 19/03/2025:

This study is an open-label non-randomized controlled trial.

Participants will be divided into 2 groups.

The first group will receive conventional therapy (methotrexate 15mg/week and tofacitinib 10mg/day) + "Eryxin" on a specialized intravenous regimen for 30 days (from day 1 to 10 - 1 ml 2 times a day, from day 11 to 30 - 2 ml 2 times a day).

The second group will receive conventional therapy (methotrexate 15mg/week and tofacitinib 10mg/day) for 30 days.

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Previous interventions:

This study is an open-label randomized controlled trial.

Participants will be divided into 2 groups. Participants will be randomized by block randomization. Block size - 4.

The first group will receive conventional therapy (methotrexate 15mg/week and tofacitinib 10mg/day) + "Eryxin" on a specialized intravenous regimen for 30 days (from day 1 to 10 - 1 ml 2 times a day, from day 11 to 30 - 2 ml 2 times a day).

The second group will receive conventional therapy (methotrexate 15mg/week and tofacitinib 10mg/day) for 30 days.

## Intervention Type

Drug

## Phase

Phase I

## Drug/device/biological/vaccine name(s)

Eryxin, Methotrexate, Tofacitinib

## Primary outcome(s)

Current primary outcome measure as of 11/04/2025:

Tolerability will be assessed throughout the study (from the first use of the study drug) using the following data:

1. Adverse event report data
2. Physical examination data, vital signs (BP, HR, HRD, body temperature)

3. Pain will be measured using a visual analogue scale (VAS) on day 1 and day 30
4. Inflammation activity of rheumatoid arthritis will be measured using the Disease Activity Score-28 (DAS-28) index on day 1 and day 30

Previous primary outcome measure:

Tolerability will be assessed throughout the study (from the first use of the study drug) using the following data:

1. Adverse event report data
2. Physical examination data, vital signs (BP, HR, HRD, body temperature)
3. Pain will be measured using a visual analogue scale (VAS) on day 1, day 10, and day 30
4. Inflammation activity of rheumatoid arthritis will be measured using the Disease Activity Score-28 (DAS-28) index on day 1, day 10 and day 30

### **Key secondary outcome(s)**

Current secondary outcome measure as of 11/04/2025:

1. Immunological changes measured using flow cytometry (CD3, CD4, CD8 cells) and ELISA (IL-1, IL-6, TNF) at day 1 and day 30

Previous secondary outcome measure:

1. Immunological changes measured using flow cytometry (CD3, CD4, CD8 cells) and ELISA (IL-1, IL-6, TNF) at day 1, day 11-15, and day 30

### **Completion date**

30/04/2025

## **Eligibility**

### **Key inclusion criteria**

1. Adults aged 18 years old and over
2. Written informed consent to participate in the study
3. With rheumatoid arthritis

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Pregnancy
2. Lactation

3. Children aged under 18 years old
4. Presence of hypersensitivity to the drug components
5. Patient's participation in other clinical trials within the last 30 days
6. Absence of informed written consent of the patient to participate in a clinical trial
7. Hypersensitivity to the drug
8. Genetically determined glucose-6-phosphate dehydrogenase deficiency (risk of hemolytic anemia)
9. History of gastrointestinal bleeding or perforation associated with NSAID therapy
10. Active peptic ulcer/bleeding or a history of recurrent peptic ulcer/bleeding (two or more cases of confirmed ulcer or bleeding)
11. Hypersensitivity reactions (symptoms of asthma, rhinitis, angioedema, or urticaria) to other NSAIDs, including aspirin
12. Severe liver dysfunction
13. Severe impairment of renal function
14. Chronic heart failure in decompensation stage

**Date of first enrolment**

05/02/2024

**Date of final enrolment**

01/11/2024

## **Locations**

**Countries of recruitment**

Uzbekistan

**Study participating centre**

**Multidisciplinary Clinic of the Tashkent Medical Academy**

Farobiy str., 2

Tashkent

Uzbekistan

100109

## **Sponsor information**

**Organisation**

Namangan Pharm Plant LTD

## **Funder(s)**

**Funder type**

Industry

## Funder Name

Namangan Pharm Plant LTD

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Umidbek Akbarov (akbarov.umid@gmail.com).

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                                   | Details    | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|------------|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a>                 |            |              | 14/04/2025 | No             | No              |
| <a href="#">Participant information sheet</a> | in Russian |              | 07/02/2024 | No             | Yes             |
| <a href="#">Protocol file</a>                 | in Russian |              | 14/04/2025 | No             | No              |