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

Submission date	Recruitment status	[_] Prospectively registered
02/02/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2024	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/04/2025	Musculoskeletal Diseases	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ЭРИН36/35ОС/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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
See outputs table

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

Pharmaceutical study type(s)
Pharmacodynamic

Phase
Phase I

Drug/device/biological/vaccine name(s)
Eryxin, Methotrexate, Tofacitinib

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/09/2023

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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
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Sponsor information

Organisation
Namangan Pharm Plant LTD

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Namangan Pharm Plant LTD

Results and Publications

Publication and dissemination plan
Planned a publication in a high-impact peer-reviewed journal

Intention to publish date
01/06/2025

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?
Participant information sheet	in Russian		07/02/2024	No	Yes
Basic results			14/04/2025	No	No
Protocol file	in Russian		14/04/2025	No	No