

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

**A Phase III, randomized, two armed, parallel, double blinded, active controlled non-inferiority to evaluate the efficacy and safety of PerkinRA (manufactured by Persisgen Par CO) in comparison with Kineret (Reference product, manufactured by SOBi ) in systemic Juvenile idiopathic arthritis.**

### Protocol summary

#### Study aim

Evaluate the efficacy and safety of PerkinRA ( manufactured by PersisgenPar CO) in comparison with Kineret (Reference product, manufactured by SOBi )

#### Design

A Phase III, Randomized,Two armed, Parallel, Double blinded (volunteers and analysis team), Active controlled Non-inferiority. Target sample size : 72 volunteers. In two groups candidate and reference product

#### Settings and conduct

This study will be performed on children with systemic JIA based on the ILAR 2018 criteria that will be treated in the Rheumatology Department of Mofid Hospital, Children's Medical Center, Afzalipour hospital, Namazi hospital and 17 shahrivar hospital between 1398 and 1400. Methods are standardized absolutely and discrepancies in evaluation criteria and study design are reduced by researcher's sessions, pre-study training for staff and Exact monitoring during the study .

#### Participants/Inclusion and exclusion criteria

Age under 16 years, weight at least 10 kg, Systemic Juvenile Arthritis subject based on ILAR criteria, obtaining written informed consent from patients

#### Intervention groups

Two groups: First group administer candidate drug (PerkinRA) subcutaneously (1-2 mg/kg) and second group administer Kineret (reference product) subcutaneously (1-2 mg/kg) For both groups the maximum dose is 100 mg daily. In both groups drugs will be injected at the first of study, after 1, 2, 4, 8, 12, 16, 20, 24 weeks of first injection.

#### Main outcome variables

The therapeutic response is based on ACR30 which includes: 1) Number of swollen joints (28 joints) 2)

Number of painful joints (28 joints) 3) Overall assessment of the severity of the disease by physician 4) Overall assessment of the severity of the disease by patient 5) Physical ability of the patient based on CHAQ criteria 6) Levels of ESR or CRP (laboratory markers)

### General information

#### Reason for update

Increasing the number of patient enrollment centers

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20190630044054N1**

Registration date: **2020-02-25, 1398/12/06**

Registration timing: **prospective**

Last update: **2020-12-16, 1399/09/26**

Update count: **1**

#### Registration date

2020-02-25, 1398/12/06

#### Registrant information

##### Name

Reza Shiari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2222 7033

##### Email address

shiareza@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

**Expected recruitment start date**

2020-05-19, 1399/02/30

**Expected recruitment end date**

2021-09-23, 1400/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A Phase III, randomized, two armed, parallel, double blinded, active controlled non-inferiority to evaluate the efficacy and safety of PerkinRA (manufactured by Persisgen Par CO) in comparison with Kineret (Reference product, manufactured by SOBi ) in systemic Juvenile idiopathic arthritis.

**Public title**

Clinical trial of PerkinRA in comparison with Kineret® (manufactured by SOBi)

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Under the age of 16 Weight at least 10 kg Systemic Juvenile Arthritis subject based on ILAR criteria (2018 version) Obtaining informed consent from patients

**Exclusion criteria:**

Positive PDD Test Patients with active hepatitis B and C Patients with antibody titre against peripheral antigen of hepatitis B OR hepatitis C History of HIV infection Patients with history of thrombocytopenia or leukopenia Hemoglobin level less than 7.5 g/dl Patients with Aspartate aminotransferase (AST) and Alanine aminotransferase (ALT) 2 times higher than the normal range. Patients with active infection (based on relevant tests and urine culture) so that been treated with injectable antibiotics within 8 weeks before screening, or with oral antibiotics within 2 weeks before screening. Patients with a history of malignancy during the 5 years before screening based on sinuses radiography and sampling If the patient is receiving corticosteroids and dose change the during 1 week before study Administration of Anakinra, Canakinumab or any Interleukin 1 inhibitors drugs. Administration of live-attenuated vaccines within 2 weeks before study or have plan for it during the study. History of allergic reaction to biologic agents or any constituents of formulation. Patients with Kawasaki based on echocardiography

**Age**From **1 year** old to **16 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

- Data and Safety Monitoring Board

**Sample size**Target sample size: **72****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization sequences for patients will be made online in sealedenvelope.com. This randomization sequence is consist of quadruple permuted balanced blocks to achieve the target sample size of 72 volunteers which its allocation ratio is 1:1. Each of these sequences will be converted to untitled codes of two letter and one number. and then four letters (corresponding to initial alphabets of volunteer's name and family name ) are added to these codes. CRO is in charge of creating random codes. Concealment: Randomization sequences will be made before starting the study and unique codes which be assigned to each patient and his pack. So the sequences will be stay covered from everyone. Packages contain 28 syringes and there will be codes and research label based on sequences on packages and syringes .

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is designed as a double blind one. all actions due to research labeling, including: take off labels, relabel as standard research labeling will be done in AryoGen. Date and exact place of this procedure will be announced officially to regulatory and supervision team. product which is produced by Persisgen Par is designed exactly the same as originator. all syringes which are used in this study will be packed in invisible 7 syringes box. all packed will be sealed by single use label. randomization codes will be assigned on this packs. based on this scenario patient and clinical outcome assessor will be blind to patient allocation to treatment groups and the data will be sent to data management team as coded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shahid Beheshti University of Medical Science

**Street address**

Research and technology deputy, Building no. 2, Shahid Beheshti University of Medical Science, Evin

**City**

Tehran

**Province**

Tehran

**Postal code**

134423235

**Approval date**

2020-02-09, 1398/11/20

**Ethics committee reference number**

IR.SBMU.REC.1398.161

**2****Ethics committee****Name of ethics committee**

Deputy of research and technology of Tehran university of medical sciences

**Street address**

Keshavarz Blv, Qods street, University Central organization, sixth floor

**City**

Tehran

**Province**

Tehran

**Postal code**

1417613151

**Approval date**

2020-03-01, 1398/12/11

**Ethics committee reference number**

IR.TUMS.VCR.REC.1398.992

**Health conditions studied****1****Description of health condition studied**

Systematic Juvenile Idiopathic Arthritis

**ICD-10 code**

M08.0

**ICD-10 code description**

Unspecified juvenile rheumatoid arthritis

**Primary outcomes****1****Description**

Medical response based on American College of Rheumatology (ACR)

**Timepoint**

At the first of study, After 12 weeks of first visit, After 24 weeks of first visit

**Method of measurement**

Percentage of disease's progress based on doctor's opinion (score 0-10), general evaluation of patients with visual chart (score 0-10), Performance Ability Based on Standardized and Validated Child Health Assessment Questionnaire (CHAQ), Number of inflamed joints based on doctor's examination, Number of joints with limited movement based on physician examination, ESR and CRP reduction

**Secondary outcomes****1****Description**

ACR 30 response

**Timepoint**

Week-4 to -8, 12, 24

**Method of measurement**

ACR 30 Questionnaire including Number of tender joints, Number of swollen joints, Patient assessment of pain, Patient's global assessment of disease activity, Physician's global assessment of disease activity, HAQ-DI, ESR, CRP

**2****Description**

Treatment response in overall assessment of disease ratio

**Timepoint**

Week-4 to -8, 12, 24

**Method of measurement**

Based on patient assessment

**3****Description**

Decrease in inflamed joints ratio

**Timepoint**

Week-4 to -8, 12, 24

**Method of measurement**

Based on physician examination

**4****Description**

Decrease in number of joints with movement restriction ratio

**Timepoint**

Week-4 to -8, 12, 24

**Method of measurement**

Based on physician examination

**5****Description**

Response to function improvement ratio

**Timepoint**

Week-4 to -8, 12, 24

**Method of measurement**

Based on standardized and validated CHAQ Persian questionnaire

**6****Description**

Decrease in CRP and ESR level

**Timepoint**

Week-4 to -8, 12, 24

**Method of measurement**

Laboratory test

**7****Description**

ADE

**Timepoint**

Day 0, weeks 1, 2, 4, 8,12, 16, 20, 24

**Method of measurement**

Questionnaire

**8**

**Description**

Changes in findings related to physical examination

**Timepoint**

Screening visit, day 0, and weeks 1, 2, 4, 8, 12, 16, 20, 24

**Method of measurement**

Questionnaire

**9**

**Description**

Vital Sign Record

**Timepoint**

Screening visit, day 0, and weeks 1, 2, 4, 8, 12, 16, 20, 24

**Method of measurement**

Body Temperature, Respiratory Rate, Blood Pressure, Heart Rate

**10**

**Description**

Systemic Immunological assessment

**Timepoint**

Screening Visit, Week 12, 24

**Method of measurement**

Clinical Lab Tests (LFT, Kidney Function, CBC and Biochemical Tests)

**11**

**Description**

Immunogenicity

**Timepoint**

Day 0, Weeks 12, 24

**Method of measurement**

Antibody against Drug evaluation

**12**

**Description**

The ratio of respondents to treatment in the overall activity rate of the disease

**Timepoint**

Screening visit, week 12 and 24

**Method of measurement**

Based on patient assessment

**Intervention groups**

**1**

**Description**

Intervention group: 100mg/ 0.67ml prefilled syringe (manufactured by Persisgen Par), subcutaneous

injection, dose 1-2 mg/kg to maximum 100 mg, which is injected by the nurses (in all visits) and by patients or his/her parents daily. site of injection should be rotated daily to reduce the risk of pain and hematoma. also the site of injection should be cooled by ice to reduce the pain.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: 100mg/ 0.67ml prefilled syringe (manufactured by SOBi), subcutaneous injection, dose 1-2 mg/kg to maximum 100 mg, which is injected by the nurses (in all visits) and by patients or his/her parents daily. site of injection should be rotate daily to reduce the risk of pain and hematoma. also the site of injection should be cooled by ice to reduce the pain.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rheumatology Department, Mofid Children Hospital

**Full name of responsible person**

Dr. Reza Shiarei

**Street address**

Rheumatology Department, Fourth Floor, Mofid Children Hospital, in front of the Hosseinieh Ershad Hospital, Dr. Shariati St., Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

15514- 15468

**Phone**

+98 21 2222 7021

**Fax**

+98 21 2222 0254

**Email**

shiareza@yahoo.com

**Web page address**

<http://mch.sbmu.ac.ir/uploads/cv-dr-reza-shiari.pdf>

**2**

**Recruitment center**

**Name of recruitment center**

Immunology and rheumatology department, Children's Medical Center

**Full name of responsible person**

Dr. Vahid Ziaee

**Street address**

No 62, Dr. Gharib St, Keshavarz Blvd, Tehran

**City**

Tehran

**Province**  
Tehran  
**Postal code**  
1419733151  
**Phone**  
+98 21 6659 5522  
**Fax**  
+98 21 6659 5525  
**Email**  
ziaee@tums.ac.ir  
**Web page address**  
<https://www.tums.ac.ir/faculties/ziaee?lang=fa>

### 3

#### **Recruitment center**

**Name of recruitment center**  
Rheumatology department, Namazi Hospital  
**Full name of responsible person**  
Dr. Shabnam Hajiani  
**Street address**  
Namazi Sq., Zand St., Shiraz  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7193613311  
**Phone**  
+98 71 3647 4332  
**Fax**  
+98 71 3647 4326  
**Email**  
sh\_h86@yahoo.com

### 4

#### **Recruitment center**

**Name of recruitment center**  
Rheumatology department, Afzali Poor Hospital  
**Full name of responsible person**  
Dr. Reza Sinaei  
**Street address**  
Emam Blvd, Kerman  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7616913911  
**Phone**  
+98 34 3132 8000  
**Fax**  
+98 34 3325 7770  
**Email**  
Sinaei.rz@gmail.com

### 5

#### **Recruitment center**

**Name of recruitment center**  
Rheumatology department, 17 Sharivar Children Hospital

**Full name of responsible person**  
Dr. Aye Mir Emarati  
**Street address**  
Saadati St, Namjoo Blvd, Rasht  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4144654379  
**Phone**  
+98 13 3336 9391  
**Fax**  
+98 13 3336 9070  
**Email**  
ayemiremarati@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**  
Persisgen Par Co.  
**Full name of responsible person**  
Dr. Amirhossein Karagah  
**Street address**  
No. 125, Before Garmdareh, 22nd Km of Karaj Roud,  
Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1399114913  
**Phone**  
+98 21 4607 4876  
**Email**  
info@persisgen.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Persisgen Par Co.

#### **Proportion provided by this source**

100

#### **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**

Trial Research Company  
**Full name of responsible person**  
Dr. Seyyed Hamed Hosseini

**Position**  
Manager of clinical trial center

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Epidemiology

**Street address**  
Unit 23, 4th Floor, NO. 1547, Tehran University of  
Medical Science Research Center, North Kargar st.,  
Before Keshavarz Blvd, Tehran

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
1417993337

**Phone**  
+98 21 8896 3546

**Email**  
ctc@tums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Dr. Reza Shiarei

**Position**  
Pediatric rheumatologist

**Latest degree**  
Subspecialist

**Other areas of specialty/work**  
Rheumatology, Pediatric

**Street address**  
Rheumatology Department, Fourth Floor, Mofid  
Children Hospital, in front of the Hosseinieh Ershad  
Hospital, Dr. Shariati St., Tehran

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
15514- 15468

**Phone**  
+98 21 2641 1681

**Email**  
shiareza@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences

**Full name of responsible person**  
Dr. Reza Shiarei

**Position**  
Pediatric rheumatologist

**Latest degree**  
Subspecialist

**Other areas of specialty/work**  
Rheumatology, Pediatric

**Street address**  
Rheumatology Department, Fourth Floor, Mofid  
Children Hospital, in front of the Hosseinieh Ershad  
Hospital, Dr. Shariati St., Tehran

**City**  
Tehran

**Province**  
Tehran

**Postal code**  
15514- 15468

**Phone**  
+98 21 2641 1681

**Email**  
shiareza@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Clinical trial data is confidential and dedicated to the company.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available