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 hosptial 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

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Name of organization / entity

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Iran (Islamic Republic of)

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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
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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

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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

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

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3

Recruitment center
Name of recruitment center
Rheumatology department, Namazi Hospital
Full name of responsible person
Dr. Shabnam Hajiani
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4

Recruitment center
Name of recruitment center
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5

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Persisgen Par Co.
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No. 125, Before Garmdareh, 22nd Km of Karaj Roud, Tehran
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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

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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