Long-term Safety Study of Kineret® in Patients With Systemic Juvenile Idiopathic Arthritis (SJIA)

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03932344	COMPLETED	APRIL 30, 2019	NOVEMBER 14, 2019

STUDY DESCRIPTION

Brief Summary

The purpose of the study is to evaluate and characterize long-term safety of Kineret when used in standard clinical practice to treat patients with systemic juvenile idiopathic arthritis (SJIA). The study will be based on already available data from the Pharmachild juvenile idiopathic arthritis (JIA) registry which holds the European Network of Centers for Pharmacoepidemiology and Pharmacovigilance (ENCePP) study seal.

Condition or Disease: Still Disease, Juvenile Onset

Intervention/treatment: Drug: Anakinra

Phase: N/A

DETAILED DESCRIPTION

This is an international, non-interventional, single-armed, pharmacovigilance registry study on long-term safety of Kineret utilizing already available data from the ENCePP certified Pharmachild JIA registry.
The Paediatric Rheumatology International Trials Organisation (PRINTO) is a non-profit, non-governmental, international research network with the goal to foster, facilitate and co-ordinate the development, conduct, analysis, and reporting of multi-centers, international clinical trials and/or outcome standardization studies in children with paediatric rheumatic diseases.
The Pharmachild JIA registry, maintained by PRINTO, is a registry collecting data from patients with JIA including patients with SJIA. In the Pharmachild JIA registry 40 countries are participating of which 15 countries have collected data on Kineret treatment.
This study includes secondary use of data already available in the Pharmachild JIA registry.

STUDY DESIGN

Study Type: Observational

Estimated Enrollment : 306 participants

Intervention Model : N/A

Masking: N/A

Primary Purpose: N/A

Official Title: A Non-interventional, Post-authorization Safety Study (PASS) to Evaluate Long-term Safety of Anakinra (Kineret®) in Patients With Systemic Juvenile Idiopathic Arthritis

Actual Study Start Date: April 2019

Actual Primary Completion Date: August 2019

Actual Study Completion Date: August 2019

GROUPS AND COHORTS

Groups/Cohorts	Intervention/treatment
: SJIA patients on Kineret treatment SJIA patients on Kineret treatment enrolled in the Pharmachild JIA registry	Drug: Anakinra Anakinra according to prescription

OUTCOME MEASURES

Primary Outcome Measures: 1. The occurrence of non-serious adverse events (AEs) of at least moderate severity and serious AEs (SAEs), including macrophage activation syndrome (MAS) as an event of special interest (ESI). [Time Frame: The Pharmachild registry was set up in December 2011. The first Kineret treatment, retrospectively collected in the registry, occurred in 2004. Data collected in the registry up until September 30, 2018 will be used (secondary use) in this study.]
The occurrence of non-serious AEs of at least moderate severity and serious AEs (SAEs), including MAS as an ESI. AEs (SAEs), including MAS as an ESI.
2. The duration of Kineret treatment in a real-world setting. [Time Frame: The Pharmachild registry was set up in December 2011. The first Kineret treatment, retrospectively collected in the registry, occurred in 2004. Data collected in the registry up until September 30, 2018 will be used (secondary use) in this study.]
The duration of Kineret treatment in a real-world setting.
3. The reasons for Kineret treatment discontinuation. [Time Frame: The Pharmachild registry was set up in December 2011. The first Kineret treatment, retrospectively collected in the registry, occurred in 2004. Data collected in the registry up until September 30, 2018 will be used (secondary use) in this study.]
The reasons for Kineret treatment discontinuation.

ELIGIBILITY CRITERIA

Ages Eligible for Study: (Child, Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Male and female patients with a diagnosis of SJIA as per the International League of Associations for Rheumatology (ILAR) classification criteria
- Included in the Pharmachild registry
- Ever treated with Kineret subsequently to SJIA diagnosis

Exclusion Criteria:
No specific exclusion criteria will be applied.

CONTACTS AND LOCATIONS

Contacts

Locations

Italy	IRCCS Istituto G. Gaslini	Genova

Sponsors and Collaborators

Swedish Orphan Biovitrum

Investigator

Study Director :	Karin Franck-Larsson, MD	Swedish Orphan Biovitrum

---

MORE INFORMATION

Responsible Party :	Swedish Orphan Biovitrum
ClinicalTrials.gov Identifier :	NCT03932344
Other Study ID Numbers :	Sobi.Anakin-302, ENCEPP/SDPP/28378
First Posted :	April 30, 2019
Last Update Posted :	November 14, 2019
Last Verified :	November 2019
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	Undecided
Plan Description:	It is not yet decided if there will be a plan to make IPD available.
Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Swedish Orphan Biovitrum:	*Kineret* *Anakinra Long term safety* *SJIA*
Additional relevant MeSH terms :	*Arthritis, Juvenile*