#### SUMMARY OF RESEARCH



# Summary of Research: Ten-Year Safety and Clinical Benefit from Open-Label Etanercept Treatment in Children and Young Adults with Juvenile Idiopathic Arthritis

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## **ABSTRACT**

This is a summary of the original article 'Tenyear safety and clinical benefit from open label etanercept treatment in children and young adults with juvenile idiopathic arthritis'. Juvenile idiopathic arthritis (JIA) usually appears before the age of 16. JIA causes pain, swelling, and stiffness in the joints. People with JIA receive treatment for several years until the disease goes into prolonged remission. Therefore, the long-term safety of these treatments is an important topic. Etanercept is a treatment for JIA, which acts on the body's immune system to reduce arthritis. This summary of research article describes safety and how well etanercept works in children with JIA taking it for up to 10 years.

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IRCCS Istituto Giannina Gaslini, UOC Gaslini Trial Centre/Servizio di Sperimentazioni Cliniche Pediatriche/PRINTO, Via Gaslini 5, 16147 Genoa, Italy e-mail: nicolaruperto@gaslini.org Summary of Research: Ten-year safety and clinical benefit from open-label etanercept treatment in children and young adults with juvenile idiopathic arthritis



PEER-REVIEWED FEATURE

Jelena Vojinović, Ivan Foeldvari, Joke Dehoorne, Violeta Panaviene, Gordana Susic, Gerd Horneff, Valda Stanevica, Katarzyna Kobusinska, Zbigniew Zuber, Bogna Dobrzyniecka, Tadej Avcin, Cecilia Borlenghi, Edmund Arthur, Chuanbo Zang, Vassilis Tsekouras, Bonnie Vlahos, Alberto Martini, Nicolino Ruperto for the Paediatric Rheumatology International Trials Organisation (PRINTO)

### Key takeaway:

Children and young adults with juvenile idiopathic arthritis took etanercept for up to 10 years. In this study, etanercept was well tolerated, and patients had durable responses while taking etanercept.

## What did this study look at?

- In this study, young people with juvenile idiopathic arthritis (JIA) from several countries took etanercept for up to 10 years.
- Participants were between 2 and 17 years old at the start of the study when they started taking etanercept. By the end of the study some of the participants were adults (aged over 18 years).
- In this summary, researchers looked at the effects of etanercept in young people with JIA when taking it for up to 10 years. Researchers wanted to answer 2 questions:
  - How many people developed cancer or serious infections?
    - Etanercept reduces the activity of some parts of the immune system, increasing the likelihood of developing side effects such as infections (common side effect) or cancer (rare side effect).
  - How many people went into remission (defined as the absence of disease signs and symptoms for at least 6 months while taking etanercept)?

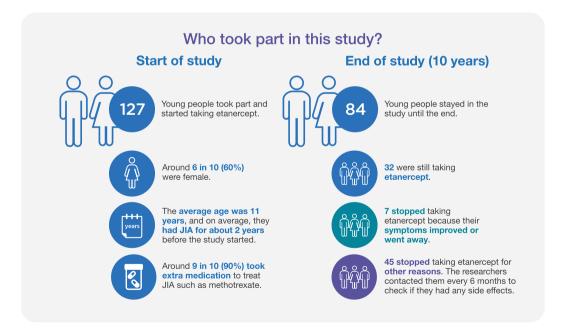
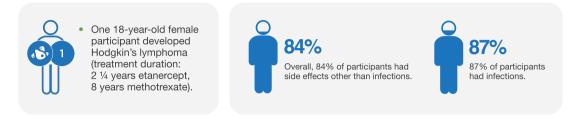
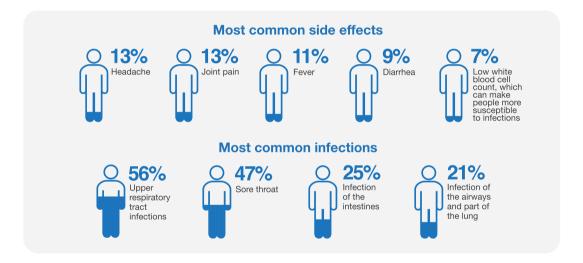


Fig. 1 Summary of research

## What were the results of the study over the course of 10 years?



- There were no cases of tuberculosis and no deaths.
- · About 24% of participants had serious side effects (excluding infections and injection site reactions).
- Most infections were mild to moderate and probably not related to etanercept.



- The researchers also looked at the efficacy of etanercept:
  - From 2 months after starting treatment until the end of study, at least 45% of people saw an improvement of their JIA symptoms by at least 50%.
  - Around 30% of people were in remission for a period of at least 12 months.
  - These percentages (or response rates) remained stable throughout the study.

#### What were the main conclusions reported by the researchers?

- In this study, 1 person developed Hodgkin's lymphoma. There were no cases of tuberculosis and no deaths.
- Most participants experienced side effects, but most of them continued to take etanercept to control their symptoms. This is similar to results from other etanercept studies.
- Reductions in symptoms were long-lasting.
- Researchers concluded that, in this study, children and young adults with JIA who took etanercept for up to 10 years experienced few serious side effects with long-lasting control of their symptoms.

#### **Primary publication**

Vojinović J, et al. Ten-year safety and clinical benefit from open-label etanercept treatment in children and young adults with juvenile idiopathic arthritis. *Rheumatology* 2024;63:140–148.

Fig. 1 continued

### SUMMARY OF RESEARCH

This is a summary of a peer-reviewed article previously published in the journal Rheumatology: Vojinović J, Foeldvari I, Dehoorne J, et al. Ten-year safety and clinical benefit from open-label etanercept treatment in children and young adults with juvenile idiopathic arthritis. Rheumatology (Oxford). 2024;63(1):140–148. [1]. Reproduced by permission of Oxford University Press on behalf of the British Society for Rheumatology (Fig. 1).

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Author Contributions. The trial was designed jointly by PRINTO investigators (NR, AM) and the sponsor. Data were collected by the PRINTO investigators. The sponsor was involved in the overall management of the trial, data collection, and data analysis. All authors reviewed and approved the final document.

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**Data Availability.** Upon request, and subject to review, Pfizer will provide the data that support the findings of this study. Subject to certain criteria, conditions and exceptions, Pfizer may also provide access to the related individual de-identified participant data. See https://www.pfizer.com/science/clinical-trials/trial-data-and-results for more information.

#### **Declarations**

Conflict of Interest. Please see the original article for full author disclosures. Edmund Arthur is now an employee of Johnon & Johnson and Bonnie Vlahos is now retired.

*Ethical Approval.* This article is based on previously conducted studies and does not contain any new studies with human participants or animals performed by any of the authors. Please see the referenced article for ethics relating to the original study.

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1. Vojinović J, Foeldvari I, Dehoorne J, et al. Tenyear safety and clinical benefit from open-label etanercept treatment in children and young adults with juvenile idiopathic arthritis. Rheumatology. 2024;63:140–148. https://doi.org/10.1093/rheumatology/kead183