

Should I take etanercept (Enbrel®) for rheumatoid arthritis?

A Cochrane decision aid to discuss options with your doctor

This decision aid is for you if:

- Your doctor says you have active rheumatoid arthritis
- You have tried methotrexate treatment and it is not working well enough.
- Your doctor has offered you etanercept (Enbrel®)

How is Rheumatoid Arthritis (RA) managed when methotrexate is not working?

RA causes your immune system to attack and inflame the lining of your joints. Often starting in the hands and feet, they become hot, swollen, stiff and painful. Without treatment, inflammation permanently destroys the joints. Therefore early treatment with drugs such as methotrexate is important. If methotrexate is not controlling the inflammation, people are advised to take stronger 'biologic' treatments such as etanercept (Enbrel®). It blocks a substance called TNF, which causes inflammation. There are several different biologic drugs which all work by blocking cells and substances in the body that contribute to the inflammation and joint damage.

What are your treatment options?



Take etanercept (Enbrel®): Once or twice a week, you have an injection under the skin in different parts of the thigh or abdomen. A nurse or doctor teaches you how to do this. A family member or friend can also learn. You store the drug in a refrigerator and warm it to room temperature prior to use. Most people who fear self-injection are able to give these injections with mild or no discomfort.



Decline etanercept (Enbrel®). You may wish to discuss other treatment options with your doctor.

What other factors may affect your choice?

Check any that apply and discuss your concerns with your doctor.

- | | |
|---|---|
| <input type="checkbox"/> I have had a previous side effect to a biologic such as anakinra (Kineret®), abatacept (Orencia®), adalimumab (Humira®), certolizumab pegol (Cimzia®), etanercept (Enbrel®), golimumab (Simponi®), infliximab (Remicade®), rituximab (Rituxan®), tocilizumab (Actimera®) | <input type="checkbox"/> I have a current infection |
| <input type="checkbox"/> I am allergic to latex | <input type="checkbox"/> I have a history of recurring infections in the chest (pneumonia), bladder, bowel, teeth, or skin including shingles |
| <input type="checkbox"/> I have the following drug allergies: | <input type="checkbox"/> I or someone in my family has had multiple sclerosis (MS) |
| <input type="checkbox"/> I have had TB | <input type="checkbox"/> I have cancer or used to have cancer |
| <input type="checkbox"/> I have lived with someone who had TB | <input type="checkbox"/> I have congestive heart failure |
| <input type="checkbox"/> I have had a positive skin test for TB | <input type="checkbox"/> I am pregnant or planning on becoming pregnant |
| <input type="checkbox"/> I have been vaccinated for TB- BCG vaccine | <input type="checkbox"/> I am breast feeding |
| | <input type="checkbox"/> I have recently had surgery or am planning to have it |

Working through the 4 steps of this decision aid may help you consider the options.

Step 1: What are the benefits and harms of each option?

Blocks of 100 faces show a 'best estimate' of what happens to **100 people** who either take etanercept (Enbrel®) or placebo (fake treatment). Each face (☺) stands for one person. The shaded areas show the number of people affected.



Benefits ++

If people take etanercept (Enbrel®) along with their usual drugs for 1 year, 29 more of them will **have a major improvement in the pain, disability, and number of tender and swollen joints**. NNT = 3*

(Improvement was measured by ACR 50 meaning that the people had at least 50% (major) improvement in their RA)

If people take etanercept (Enbrel®) for 10 years, 11 fewer people will have **serious joint damage** as seen on X-rays.

Take etanercept (Enbrel®) injection plus usual drugs

50 Improve
50 Don't improve



96 Avoid permanent joint damage

4 get joint damage



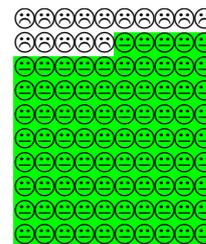
Take placebo injection plus usual drugs

21 Improve
79 Don't improve



85 Avoid permanent joint damage

15 get joint damage



Side Effects ++

Etanercept causes 3 more people who take etanercept (Enbrel®) for 1 year to **stop treatment** due to side effects such as a skin reaction. Reactions include rash, burning, or itching at the injection site. This may last 10 to 14 days without leaving a scar.

13 Stop treatment

87 Stay on treatment



10 Stop treatment

90 Stay on treatment



Serious Harms +

If **10,000** people take etanercept (Enbrel®) for 1 year, 16 more people may get **tuberculosis** from taking it. If you live in a place where TB is rare, the chance will be lower. Before starting etanercept, a TB test is usually done. The drug is stopped if people have a high fever or have an active infection and are taking an antibiotic.

9,980 Avoid tuberculosis

20 Get tuberculosis

9,996 Avoid tuberculosis

4 Get tuberculosis

+Note: The options include 'estimates' of what happens to groups of people based on the available research. The quality of these estimates is rated summarized using the GRADE system as follows: ++++ **High** quality – further research is **very unlikely to change** the estimate. +++ **Moderate** quality – further research **may change** the estimate. ++ **Low** quality – further research is **likely to change** the estimate. + **Very low** quality – further research is **very likely to change** the estimate. **NNT stands for number needed to treat. It is a way of showing how many people must take a drug for one person to benefit. For example, 3 people would need to take Etanercept for one person to benefit (improved pain and dysfunction).

Step 2. What matters most to you?

Common reasons to choose each option are listed below.

Check how much each reason matters **to you** on a scale from 0 to 5.

'0' means it is **not** important to you. '5' means it is **very** important to you.

 Reasons to take etanercept (Enbrel®)	Not Important			Very Important		
	0	1	2	3	4	5
How important is it to you to improve your symptoms of rheumatoid arthritis?	<input type="checkbox"/>					
How important is it to you to reduce your chance of serious joint damage?	<input type="checkbox"/>					
List other reasons to take etanercept (Enbrel®):	<input type="checkbox"/>					

 Reasons to decline etanercept (Enbrel®)	Not Important			Very Important		
	0	1	2	3	4	5
How important is it to you to avoid injections?	<input type="checkbox"/>					
How important is it to you to avoid the extra risk of tuberculosis?	<input type="checkbox"/>					
List other reasons to decline etanercept (Enbrel®):	<input type="checkbox"/>					

Now, thinking about the reasons that are most important to you...

Which option do you prefer?

Check one.

- I don't know
- Take etanercept (Enbrel®)
- Decline etanercept (Enbrel®)
- Discuss other treatment options

Step 3: What else do you need to prepare for decision making?

Find out how well this decision aid helped you learn the key facts.

Check the best answer.

	Take etanercept (Enbrel®)	Decline etanercept (Enbrel®)	I don't know
1. Which option <u>raises</u> your chance of improving pain, dysfunction, and the number of swollen joints?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Which option <u>lowers</u> your chance of serious joint damage?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Which option has a greater risk of skin reactions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Which option has the <u>lowest</u> chance of tuberculosis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Check your answers at the bottom of the page

Find out how comfortable you feel about deciding

Yes No



Do you know enough on the benefits and harms of each option to make a choice?



Are you clear about which benefits and harms matter most to you?



Do you have enough support and advice to make a choice?



Do you feel sure about the best choice for you?

If you answered 'No' to any of these, discuss with your practitioner. (Adapted SURE Test © O'Connor & Légaré)

Step 4: What are the next steps?

Check what you want to do next...

- Try etanercept (Enbrel®)
- Discuss other treatment options
- Other, please specify:

Step 3 answers: Questions 1, 2 and 3: Take etanercept (Enbrel®) Question 4. Decline etanercept (Enbrel®)

This information is not intended to replace the advice of a health care provider

This decision aid was developed by Rader, T. Maxwell, L. Ghogomu, E. Tugwell, P. Welch, V. Conflict of interest disclosure available from trader@uottawa.ca. Funded in part by the Canadian Institutes of Health Research. Format based on the Ottawa Personal Decision Guide © 2000, A O'Connor, D Stacey, University of Ottawa, Canada. Last reviewed: July 2011. Acknowledgements: J. Karsh, MD, FRCPC provided scientific and clinical review of this aid. G. Wells converted Vanderheid-Sharp scores using Wells Calculator. References on outcomes from: 1. Singh JA et al. Biologics for rheumatoid arthritis: an overview of Cochrane reviews. Cochrane Database of Systematic Reviews 2009, Issue 4. 2. Singh et al. Adverse effects of biologics: a network meta-analysis and Cochrane overview. Cochrane Database of Systematic Reviews 2010, Issue 10. Art. No.: CD008794. DOI: 10.1002/14651858.CD008794.pub2. Information on clinical meaning of x-ray damage: Smolen JS, Aletaha D, Grisar JC, Stamm TA, Sharp JT. Estimation of a numerical value for joint damage-related physical disability in rheumatoid arthritis clinical trials. Ann Rheum Dis. 2010 Jun;69(6):1058-64.

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