Should I take tocilizumab (Actemra®) for rheumatoid arthritis?

A Cochrane decision aid to discuss options with your doctor

This decision aid is for you if:

You are 16 or older.

□ Your doctor has told you that you have active rheumatoid arthritis (RA).

What is rheumatoid arthritis (RA)?

When you have rheumatoid arthritis, your immune system, which normally fights infection, attacks the lining of your joints making them inflamed. This inflammation causes your joints to be hot, swollen, stiff, and painful. The small joints of your hands and feet are usually affected first. If the inflammation goes on without treatment, it can lead to damaged joints. Once the joint is damaged it cannot be repaired, so treating rheumatoid arthritis early is important.

What is tocilizumab?

tocilizumab is one of the biologic medicines that blocks a protein called interleukin-6 (IL-6). tocilizumab stops the inflammation that is caused by having too much IL-6 in the body. Even though suppressing the immune system can make it slightly harder to fight off infections, it also helps to stabilize an overactive immune system. By reducing the inflammation, the aim is to help prevent damage to the joints. Tocilizumab is given by an intravenous infusion (IV) by a trained nurse in a clinic. Each infusion takes about an hour.

What are your options?

- tocilizumab
- I will discuss the other treatment options with my doctor.

What other health factors may affect your choice?

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

Have you had a previous severe side-effect to a biologic (Adalimumab (Humira®), Infliximab (Remicade®), Etanercept (Enbrel®), Abatacept (Orencia®), or Rituximab (Rituxan®)?
Have you ever or do you currently have cancer?
Have you ever had congestive heart failure?
Have you or anyone in your family ever been diagnosed with multiple sclerosis?
Do you have a current infection?
Do you have a history of recurring infections such as chest infections (pneumonia), bladder infections,
skin infections (including shingles), bowel infections, tooth infections, or any other type of infections?
Have you ever been diagnosed with tuberculosis (Tb)?
Do you know or have you ever lived with anyone with Tb?
Have you ever had a positive skin test for Tb?
Have you ever been vaccinated for Tb – BCG vaccine?
Are you currently pregnant or breast feeding?
Are you planning on becoming pregnant?
Do you have any drug allergies?
Do you have an allergy to Latex?

Checklist developed by Andy Thompson MD FRCPC (Revised November, 2007), ©2007 Available at www.RheumInfo.com

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

What does the research show?

Blocks of 100 faces show a 'best estimate' of what happens to 100 people who had tried tocilizumab. Each face (©) stands for one person. The shaded areas show the number of people affected. There is no way of knowing in advance if you will be affected.

Benefits ++++

People who had a 50% improvement in the number of tender or swollen joints and other outcomes such as pain and disability (ACR 50) up to 24 weeks.

NNT=5*

21 more people who took tocilizumab had a 50% improvement in the number of tender or swollen joints and other outcomes such as pain and disability (ACR 50). (NNT: 5)

tocilizumab	Placebo
69 Do not improve	90 Do not improve
31 Improve	10 Improve
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Side effects ++++

People who stopped treatment due to side effects up to 24 weeks.

2 more people who took tocilizumab stopped treatment due to side effects. This may have happened by chance.

We do not have precise information about side effects and complications, especially for rare but serious side effects. Possible side effects include nausea, headache and tiredness. Rare complications may include bowel problems or an allergic reaction. It is important to keep medical appointments to catch any serious adverse events early.

95	avoid side
	effects

5	stop treatment
36	<mark>8888</mark> @@@@@

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93 avoid side effects

3	stop	treatment

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Note: The options include 'estimates' of what happens to groups of people based on the available research. The quality of these estimates is 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.

Step 2: Which reasons to choose each option matter most to you?

Common reasons to choose each option are listed below. Check \checkmark how much each reason matters <u>to you</u> on a scale from 0 to 5. '**0**' means it is **not** important to you. '**5**' means it is **very** important to you.

How important is it to you							
not important					very important		
to have 50% improvement in the number of tender or swollen joints and other outcomes such as pain and disability in your RA?	→ No tocilizumab	0	1	2 3) 4	\$	tocilizumab
to avoid adverse events or side effects?	tocilizumab ®	1	2	3	4	⑤ No	o tocilizumab
to avoid taking medicine by injection?	tocilizumab ®	1	2	3	4	⑤ No	o tocilizumab
to avoid the high cost of biologics?	tocilizumab ©	1	2	3	4	⑤ No	o tocilizumab
List other reasons that are important:							
		0 (D 2	3	4	(5)	
		0 (D 2	3	4	(5)	
	,	0 (D 2	3	4	\$	

Now, think about which option has the reasons that are most important to you.

Which option do	you	prefer?	Check $\ensuremath{\square}$ one.
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☐ Tocilizumab

☐ I will discuss the other treatment options with my doctor

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

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Knowledge

Find out how well this decision aid helped you learn the key facts. 1. Which option has the **highest** chance of improving symptoms of rheumatoid Tocilizumab No tocilizumab arthritis? 2. tocilizumab is taken as an pill. False True 3. If 100 people take tocilizumab, how many П П people had a 50% improvement in the 10 29 50 Don't know number of tender or swollen joints and other outcomes such as pain and disability? 4. If 100 people take tocilizumab, how many people will have side effects? Don't know Check your answers at the bottom of the page. Yes Do you know enough about the benefits and side effects of taking П \Box tocilizumab? Values Are you clear about which benefits and side effects matter most to you? \Box Support Do you have enough support and advice from others to make a choice? Uncertainty \Box П Do you feel sure about the best choice for you? Step 4: What are the next steps? □ I will take tocilizumab ☐ I need more information and I will discuss the options with my doctor

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

Answers for key facts: 1. tocilizumab 2. False 3. 29 4. 2

This decision aid was developed by Rader, T. Maxwell, L. Ghogomu, E. Tugwell, P. Welch, V. Conflict of interest 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: February 2011.

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Information on benefits and harms from: Singh JA, Beg S, Lopez-Olivo MA. tocilizumab for rheumatoid arthritis. Cochrane Database of Systematic Reviews 2010, Issue 7. Art. No.: CD008331. DOI: 10.1002/14651858.CD008331.pub2.

