

# Should you take steroids and immunosuppressive agents for lupus kidney disease? Facts and decision aid

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## What is lupus kidney disease?

SLE (systemic lupus erythematosus) or, simply “lupus”, is a group of diseases in which the body’s immune system does not work right. In a healthy person, the body’s immune system fights or attacks germs but with lupus the body starts to attack itself. Lupus can cause swelling, pain and damage to many organs of the body such as the skin, heart, lungs, brain and kidneys. When people with lupus have kidney problems or kidney disease, it is called SLE nephritis or lupus kidney disease.

Lupus usually happens in cycles, where there are times when you have pain and illness or times when you have little or no pain and illness (remission). If the swelling is not treated, it can cause damage that does not go away. In lupus kidney disease, pain and swelling in the kidney can cause long-term damage that can lead to:

- swollen feet and legs
- a need for dialysis or kidney transplant
- kidneys stop working
- death

## What can you do on your own to manage your disease?

- Be active
- Avoid alcohol
- Relax

## What treatments are used for lupus kidney disease?

Three kinds of treatment may be used alone or together. The common (generic) names are shown below.

### 1. Oral or IV corticosteroids

- Prednisone
- Prednisolone
- Methylprednisolone

### 2. Immunosuppressive agents (cytotoxics)

- Azathioprine
- Cyclophosphamide
- Mycophenolate mofetil

### 3. Alternative therapies

- Ciclosporin
- IV immunoglobulins

## What about other treatments you may have heard about?

There is not enough evidence about the effects of some treatments. Other treatments may not work. For example:

- Plasmapheresis (may not work)
- Dehydroepiandrosterone (DHEA) (needs more research)
- LJP 394 (needs more research)

## What are your choices? How can you decide?

Treatment for your disease will depend on your condition and your doctor’s advice. You need to know the good points (pros) and the bad points (cons) about a treatment before you can decide.

This guide can help you if your doctor recommends treatment of steroids and immunosuppressive agents.



**Step 1: Be clear about the choice**

**What are the options?**

Should you take steroids and immunosuppressive agents?

When does this choice have to be made? Check  one

- Within days                       Within weeks                       Within months

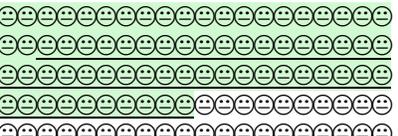
How far along are you with a choice? Check  one

- You have not thought about it yet                       You are thinking about the choices  
 You are close to making a choice                       You have made a choice

**Step 2: Think about the pros and cons of the options**

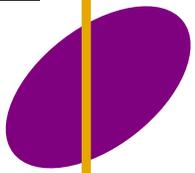
**What does the research show?**

Blocks of 100 faces show the 'best guess' for what happens to 100 people with lupus kidney disease (systemic lupus erythematosus nephritis) if they try a steroid alone, an immunosuppressive agent alone, or a combination of the two for 1 year. Each face ☺ stands for one person.

 <b>With a steroid (methylprednisone)</b>	 <b>With an immunosuppressive agent (cyclophosphamide)</b>	 <b>With a combination (methylprednisone AND cyclophosphamide)</b>
 <p><b>37</b> people may have improved kidney function (<u>26 of them had periods of little or no swelling in the kidneys – they went into renal remission</u>)</p> <p><b>63</b> people may not have improvement in kidney function</p>	 <p><b>70</b> people may have improved kidney function (<u>48 of them had periods of little or no swelling in the kidneys – they went into renal remission</u>)</p> <p><b>30</b> people may not have improvement in kidney function</p>	 <p><b>89</b> people may have improved kidney function (<u>61 of them had periods of little or no swelling in the kidneys – they went into renal remission</u>)</p> <p><b>11</b> people may not have improvement in kidney function</p>
 <p><b>93</b> have no side effects</p> <p><b>7</b> may have side effects such as serious infections, hair loss, sore bladder, blood in urine, bone loss, death of bone tissue</p>	 <p><b>59</b> have no side effects</p> <p><b>41</b> may have side effects such as serious infections, hair loss, sore bladder, blood in urine, bone loss, death of bone tissue</p>	 <p><b>57</b> have no side effects</p> <p><b>43</b> may have side effects such as serious infections, hair loss, sore bladder, blood in urine, bone loss, death of bone tissue</p>

\*\*\*\* Ribbons show the strength of results from research studies.

-  **Platinum:** Research results from a well done review of 2 or more randomised controlled studies. Each study was well done and had at least 100 people in it.
-  **Gold:** Research results from at least one well done randomised controlled study that had at least 100 people in it.
-  **Silver:** Research results from studies that were not as strong. There may have been too few people in the study or the study was not well done.
-  **Bronze:** Expert views and experiences, or cases of what happened to someone taking a treatment.



**What do you think of the pros and cons of cyclophosphamide plus steroids?**

The information below is from two reviews and 2 studies that tested steroids and immunosuppressive agents in people with lupus kidney disease (systemic lupus erythematosus nephritis). These studies lasted up to 10 weeks to 11 years.

1. Review the common pros and cons.
2. Add any other pros and cons that matter to you.
3. Show how much each pro and con matters to you. Circle one (\*) star if it matters a little to you and up to five (\*\*\*\*\*) stars if it matters a lot to you.

PROS AND CONS OF STEROIDS AND IMMUNOSUPPRESSIVE AGENTS			
PROS	How much does it matter to you?	CONS	How much does it matter to you?
Less likely to develop kidney failure or die from kidney disease	* * * * *	<b>Side effects:</b> severe infections, hair loss, sore bladder, blood in urine, bone loss, death of bone tissue	* * * * *
Improves kidney function	* * * * *	<b>Long term harms:</b> diabetes, early menopause, bladder tumours, other cancers and death	* * * * *
Improves symptoms, such as rashes, fever, arthritis, mouth sores, and swelling around the lungs and heart	* * * * *	<b>Extra clinic visits and blood tests needed</b>	* * * * *
Lowers the chances of needing kidney dialysis or kidney transplantation	* * * * *	<b>Personal cost of medicine</b>	* * * * *
Other pros:	* * * * *	Other cons:	* * * * *

**What do you think about taking cyclophosphamide plus steroids? Check  one**

You are willing to take this treatment  
Pros matter more to you than the Cons

Unsure

You are not willing to take this treatment  
Cons matter more to you than the Pros

**Step 3: What role do you want to have in choosing your treatment? Check  one**

You prefer to choose on your own after listening to the opinions of others.

You prefer to share the choice with: \_\_\_\_\_.

You prefer someone else to choose for you, namely: \_\_\_\_\_.



**Step 4: Find out what else you need to help you make the choice**

<b>Facts</b>	Do you know which options you have?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Do you know both the good <b>and</b> bad points of each option?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Values</b>	Are you clear about which good and bad points <i>matter most to you</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Support</b>	Do you have enough support and advice from others to make a choice?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Are you choosing without pressure from others?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>Certainty</b>	Do you feel sure about the best choice for you?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

*If you answered "No" to many of these questions, you should talk to your doctor.*

**Step 5: Plan the next steps**

**What do you need to do before you make this choice?**

For example – talk to your doctor, read more about this treatment and other treatments.

**Step 6: Share your answers on this form with your doctor**

It will help your doctor understand what you think about this treatment.

## Appendix A: Key Words are Defined

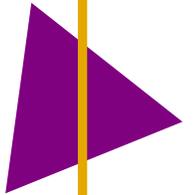
**SLE (systemic lupus erythematosus)** or, simply “lupus”, is a group of diseases in which the body’s immune system does not work right. In a healthy person, the body’s immune system fights or attacks germs but with lupus the body starts to attack itself. Lupus can cause swelling, pain and damage to many organs of the body such as the skin, heart, lungs, brain and kidneys. When people with lupus have kidney problems or kidney disease, it is called SLE nephritis.

Lupus usually occurs in cycles, where there are periods of pain and illness or periods of little or no pain and illness. If the swelling is not treated, it can cause permanent damage. In lupus kidney disease, pain and swelling in the kidney can cause permanent damage to the kidney that can lead to:

- swollen feet and legs (water retention)
- need for dialysis or kidney transplant
- kidneys stop working
- death

**Dialysis:** Healthy kidneys clean out toxic matter from the body into the urine. When kidneys are not healthy, the toxic matter may not be cleaned out, but build up in the body and cause problems. To get the toxins out, dialysis can be used. A person can be hooked up to a machine that slowly pulls blood out of the body, cleans it and then puts it back into the body. This can take a few hours to do. Or, a person may be given special fluids into their blood, which absorb the toxins and then are drained out. Dialysis could be done every day or a few days a week.

**Pain** varies from person to person. When it is severe, it can limit your daily routines at home and at work. Also, it can get in the way of how you feel about your well-being.



## Appendix B: Facts and Numbers Behind the Decision Aid

These facts are only for those who want to know more about how the decision aid was made. To make your choice, you do not need to read it.

The following are the data sources, assumptions and calculations used in this decision aid. These are the best estimates based on available data. Data are subject to review as more information becomes available.

The information presented in this patient decision aid was based on evidence referenced in Appendix C (below).

It is assumed that patients who participated in the research studies used as the data sources for this patient decision aid would be similar to patients who would use the decision aid.

**Author disclosure:** None of the authors or their institutional affiliations can gain financially from the information contained within this patient decision aid.

**Reading level:** This decision aid is estimated to be able to be understood by patients with less than grade 8 reading level. Readability was calculated using the SMOG index.

**This patient decision aid meets the following draft standards of the IPDAS Collaboration © 2004:**

- Used a systematic development process  
See credentials of review team. Physician & consumers revised the decision aid (see list of developers). The needs assessment and review is underway with patients and physicians who were not involved in its development.\*
- Provided information on the condition, options, and their outcomes  
health condition, options (including doing nothing), natural history, procedures involved, positive & negative features of options, probabilities of outcomes.
- Presented probabilities of outcomes (benefits and harms)  
Uses event rates, comparing same denominator, same period of time and balanced frames. Describes uncertainty around probabilities (our best guess), using more than one method (numbers, words, diagrams). There is no tailoring of probabilities to individual risk categories. Refers to reference of source of probabilities.
- Clarified values and suggested ways to communicate values with the practitioner  
Describes features and physical, emotional, and social effects (Summary and glossary). Asks people to think about which positive and negative features matter most using balance scales and rating exercises. Suggests patient share their worksheet with the practitioner
- Used personal stories of how others' made their decision  
Not included.
- Guided or coached in deliberation and communication.  
Uses step-by-step process. Uses worksheet and suggests sharing it with practitioner.  
No coaching offered but could be used with a coach.
- Disclosed conflicts of interest  
Funding source disclosed for development and distributing. Discloses conflicts of interest of authors and affiliations.
- Delivered the decision aid on the internet. Currently available only as a PDF on the internet.  
An interactive internet version is under development.\*
- Balanced the presentation of options.  
Compares positive and negative features with similar detail and emphasis (font, order, display). Field testing for balance is underway.\*
- Used plain language.  
Plain language specialist reviewed the decision aid and readability level < grade 8 by SMOG.
- Based information on up-to-date scientific evidence  
pending\_ Evaluated its effectiveness; currently being evaluated.\*

\* underway in CIHR grant 2004 (Brehaut, Tugwell & O'Connor)

## Appendix C: References

- Bansal VK, Beto JA. Treatment of lupus nephritis: a metaanalysis of clinical trials. *Am J Kidney Dis* 1997;29:193–9.
- Felson DT, Anderson J. Evidence for the superiority of immunosuppressive drugs and prednisone over prednisone alone in lupus nephritis. *N Engl J Med* 1984;311:1528–33.
- Gourley MF, Austin HA, Scott D, et al. Methylprednisolone and cyclophosphamide alone or in combination in patients with lupus nephritis. *Ann Intern Med* 1996;125:549–57.
- Schiffenbauer J, Chakravarty E, Strand V. Systemic lupus erythematosus. In: Tugwell P, Shea B, Boers M, Brooks P, Simon LS, Strand V, Wells G, eds. Evidence-based rheumatology. London: BMJ Books, 2004.
- Steinberg AD, Decker JL. A double blind controlled trial comparing cyclophosphamide, azathioprine and placebo in the treatment of lupus glomerulonephritis. *Arth Rheum* 1974;17:923–37.