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Leukapheresis for inflammatory bowel disease

Understanding NICE guidance –
information for people considering
the procedure, and for the public

Ordering information

You can download the following documents from www.nice.org.uk/IPG126

- this booklet
- the full guidance on this procedure.

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0874 (full guidance)
- N0875 (information for the public).

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely within the NHS. This guidance covers England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called leukapheresis for inflammatory bowel disease. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether leukapheresis is safe enough and works well enough for it to be used routinely for the treatment of inflammatory bowel disease.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of leukapheresis for inflammatory bowel disease and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 10).

About leukapheresis for inflammatory bowel disease

Ulcerative colitis and Crohn's disease are the most common types of inflammatory bowel disease. With ulcerative colitis, the rectum (back passage) and the colon (the large intestine) develop lots of ulcers and are inflamed. The person's symptoms may include bloody diarrhoea and bleeding from the rectum.

Crohn's disease usually causes inflammation and ulceration in the small intestine, though any part of the digestive system can be affected by it. The main symptoms are abdominal pain, diarrhoea and weight loss. Both Crohn's disease and ulcerative colitis are long-term conditions, and people often experience periods when the symptoms 'flare up' between periods of remission (when symptoms ease or disappear).

People with inflammatory bowel disease may be offered advice about their diet and medicines such as steroids to help control the body's immune system and calm the inflammation. If these don't help, surgery to remove some of the intestine may be an option for people with ulcerative colitis. Surgery can also be used for people with Crohn's disease, but the symptoms often come back in a different part of the intestine.

The new procedure that NICE has looked at is called leukapheresis. It involves removing a small number of white blood cells from the person's blood. It's not known exactly how leukapheresis helps in inflammatory bowel disease, but it appears to have an effect on the immune system and helps to ease inflammation.

The person is connected to a machine so that blood flows through the machine and then back into the body. The machine processes the blood so it doesn't start to clot while it's outside the body and then it takes some of the white cells out. The blood is then returned to the body.

How well the procedure works

What the studies said

In one study that involved people with ulcerative colitis, 29 out of 39 people who had leukapheresis were said to have had an 'excellent' or 'moderate' improvement in their symptoms. In comparison, 14 out of 37 people who had high doses of steroids were said to have had a similar improvement. As percentages, these are 74% of the people who had leukapheresis and 38% of the group who had steroids.

NICE also looked at four studies that followed what happened in people with ulcerative colitis after they'd had leukapheresis. The number of people who had an initial remission after the treatment went from 24 out of 44 people in one study to 32 out of 39 people in another (as percentages, this range is 54% to 82%).

In the study that involved 39 people, the number of people in remission went from 32 at 12 weeks after treatment to 26 after 12 months (a drop from 82% to 67%). In two of the other studies, the symptoms worsened again in around a third of people who had had an initial remission following the leukapheresis.

In a study that involved people with Crohn's disease, all 12 people who had leukapheresis were then taken off steroids successfully. As a comparison, this happened in 10 out of 15 people who didn't have leukapheresis. When the groups were checked on again after 18 months, similar numbers of people in both groups had had a flare up of symptoms.

What the experts said

The experts said that it wasn't completely clear how well leukapheresis worked in people with inflammatory bowel disease. Further studies would be needed.

Risks and possible problems with the procedure

What the studies said

In most of the studies, the problems linked with having leukapheresis were mild – for example, feelings of dizziness, lightheadedness, headache and flushing. The number of people having these types of side effects went from 5 out of 53 (9%) in one study to 7 out of 39 (18%) in another.

In the study that compared people who had leukapheresis with people who had high doses of steroids, 24% of the people in the leukapheresis group had problems with their treatment compared with 47% of the group that had the steroids. Among the 42 people who had leukapheresis in this study:

- 1 person developed toxic shock – blood poisoning that causes a severe illness
- 1 person had chest pain
- 1 person had anaemia – their blood became low in haemoglobin (the part that carries oxygen)
- 2 people had headaches.

What the experts said

The experts said that the possible problems linked with leukapheresis were infection, headache, palpitations (when you become aware of your heart beating), a feeling of sickness, vomiting, fever, chills, breathing problems and discomfort in the chest.

What has NICE decided?

NICE has said that there are no major concerns over the safety of this procedure and that it may help certain patients with ulcerative colitis. However, there is not yet enough evidence on how well it works and NICE has decided that, if a doctor wants to carry out leukapheresis for ulcerative colitis, he or she should make sure that the patient understands what is involved and that there are still uncertainties over how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place. The results of the procedure should be monitored.

There is not enough evidence to decide how well this procedure works for people with Crohn's disease and it should be used only under the circumstances described above.

NICE has said that further studies looking at leukapheresis for inflammatory bowel disease will provide useful information. NICE may look at the procedure again when more information becomes available.

Other comments from NICE

Leukapheresis is already used as a treatment for other conditions. There are different ways of carrying out leukapheresis and different equipment is available. Some may work better than others, and some may be linked with a higher chance of problems than others.

What the decision means for you

Your doctor may have offered you leukapheresis for inflammatory bowel disease. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about how well it works in people with inflammatory bowel disease which you need to understand before you agree to it. Your doctor should discuss these with you. Some may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on leukapheresis for inflammatory bowel disease that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you have access to the internet, you can find more information on ulcerative colitis and Crohn's disease on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.





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