

## Understanding NICE guidance

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Information for people who use NHS services

# Treating Crohn's disease using treated white blood cells

*NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.*

This leaflet is about when and how treating white blood cells can be used in the NHS to treat people with Crohn's disease. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe Crohn's disease or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

## What has NICE said?

The evidence that NICE looked at included only a very small number of patients. While the evidence shows no major safety concerns there is not enough evidence to be certain about how well this procedure works.

For these reasons, NICE has said that this procedure should only be carried out as part of a research study.

*This procedure may not be the only possible treatment for Crohn's disease. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.*

## Treating Crohn's disease using treated white blood cells

The medical name for this procedure is 'extracorporeal photopheresis for Crohn's disease'.

The procedure is not described in detail here – please talk to your doctor for a full description.

Crohn's disease is a long-term condition that usually causes inflammation and ulcers in the small intestine, although any part of the digestive system can be affected by it. The main symptoms are abdominal pain, diarrhoea and weight loss.

Treatments include medicines to control the inflammation and to reduce the chance of the condition coming back, and changes in diet. Occasionally surgery to the bowel may be offered.

The procedure normally involves collecting blood from the patient by a small tube put into a vein in the arm. The blood then flows through a machine which separates off the white blood cells, and the rest of the blood is returned to the patient. The white blood cells are treated with a light-sensitive medicine and ultraviolet light. They are then put back into the patient to try to protect the body from the cells that cause the inflammation.

The treatment usually consists of about 20 sessions.

## What does this mean for me?

Because there is very little evidence about the safety of this procedure and how well it works, your doctor can only offer you this procedure as part of a research study.

### You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

## Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at four studies on this procedure.

### How well does the procedure work?

In a study of 28 patients, symptoms had improved in 14 patients and 7 were in remission (free of symptoms), 12 weeks after treatment. In another study, steroid use was reduced by half in 8 out of 10 patients after about 10 weeks, and 4 out of 10 were in remission after about 20 weeks. Three of them remained in remission after an average of about 16 weeks.

The study of 28 patients also looked at quality of life using a questionnaire where the higher the score, the better the patient's reported quality of life. The average score improved from 122 points before treatment to 154 points 12 weeks after treatment.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the main success factors are better quality of life, a decrease in the number of stools passed, a decrease in abdominal cramps and reduced steroid use.

## Risks and possible problems

In the study of 28 patients, 2 had to stop their treatment because of side effects; 1 had nausea and the other had fever. Eight patients had headaches and a swollen pharynx (the cavity at the back of the mouth), and 5 had nausea.

In three other studies, involving a total of 14 patients, 2 had low blood pressure, 1 had a mild headache, 1 had minor bruising and 1 had problems with their immune system. In 3 patients anaemia became worse after the treatment.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that problems include low blood pressure, fits, sensitivity to light or allergy to the light-sensitive medicine, anaemia and infection caused by the thin hollow tube used to take blood. Possible but less likely problems include bleeding, and cancer caused by the ultraviolet light.

## More information about Crohn's disease

NHS Choices ([www.nhs.uk](http://www.nhs.uk)) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support.

### About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

*To find out more about NICE, its work and how it reaches decisions, see [www.nice.org.uk/aboutguidance](http://www.nice.org.uk/aboutguidance)*

*This leaflet is about 'extracorporeal photopheresis for Crohn's disease'. This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/IIPG288](http://www.nice.org.uk/IIPG288)*

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk) and quote reference N1799).*

*We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.*