

Treating HIV-related lipoatrophy by injecting a non-absorbable gel polymer

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

This document is about when and how injecting a non-absorbable gel polymer can be used in the NHS to treat people with HIV-related lipoatrophy (loss of fat from the skin). It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech 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.

This document 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 HIV-related lipoatrophy or the procedure in detail – a member of your healthcare team should give you full information and advice about these. The document includes some questions you may want to ask your doctor to help you reach a decision.

What has NICE said?

Although there is evidence to say that this procedure works, there are a number of risks. If a doctor wants to inject a non-absorbable gel polymer to treat HIV-related lipoatrophy, they should make sure that extra steps are taken to explain the uncertainty about the potential short- and long-term risks of the procedure. These include infection, inflammation and movement of the gel after the procedure, and that the gel may need to be removed by surgery. Also, the different treatments available for HIV-related lipoatrophy should be explained to the patient. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

NICE has also said that this is a difficult procedure. It should only be carried out by doctors with special training in the method used to inject the gel. They should take precautions, including carrying out the procedure in an appropriate environment, to reduce the risk of the patient getting an infection during the procedure.

NICE has encouraged further research into treating HIV-related lipoatrophy by injecting a non-absorbable gel polymer. The research should look at which patients are offered treatment compared with other treatments being used for HIV-related lipoatrophy. It should also look at how well the procedure works, whether there are any complications, and how patients manage in the long term. NICE may review the procedure if more evidence becomes available.

Other comments from NICE

NICE recognised that facial lipoatrophy can be very distressing for patients with HIV, and that their quality of life may be significantly improved by treatment.

This procedure may not be the only possible treatment for HIV-related lipoatrophy. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Treating HIV-related lipoatrophy by injecting a non-absorbable gel polymer

The medical name for this procedure is 'deep dermal injection of non-absorbable gel polymer for HIV-related lipoatrophy'.

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

HIV-related lipoatrophy is loss of fat from the skin, often from the face (the cheeks, temples and around the eyes). It can occur as a side effect of the older antiretroviral drug treatments for HIV. Changes in appearance may have severe psychological and social consequences for some people.

Treatments for HIV-related lipoatrophy help to improve the volume and shape of the affected area where fat has been lost, by injecting fat cells from another part of the body, collagen or a substance called polylactic acid. These are gradually absorbed by the body. Skin and fat grafts can also be carried out, using tissues from another part of the body.

This procedure uses non-absorbable gel polymers, which are synthetic substances that are not broken down by the body. There are a number of different kinds of gel that can be used for this procedure.

The procedure is carried out using a general or local anaesthetic. The non-absorbable gel polymer is injected deep into the tissues under the skin. It is massaged into place to make it look as natural as possible.

Once the gel is in place a thin layer forms on its surface that separates it from the surrounding tissues. The amount of gel used depends on which part of the body is affected and how severe the lipoatrophy is. The patient may need to have a course of injections over several weeks. Antibiotics are given to reduce the risk of infection.

What does this mean for me?

If your doctor has offered you injections of a non-absorbable gel polymer to treat HIV-related lipoatrophy, he or she should tell you that NICE has decided that although the procedure works there are a number of risks. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this document, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

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 care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

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 10 studies on this procedure.

How well does the procedure work?

Three studies (involving 32, 145 and 299 patients) looked at how patients felt about their appearance and how they felt in themselves 4 years after the procedure. The studies of 32 and 145 patients reported that patients felt their facial lipoatrophy improved or were satisfied with their treatment after the procedure. In the study of 299 patients, in which 130 patients had the procedure and the others were treated with different procedures, all patients felt better about their facial appearance, body image and were less depressed. The study of 32 patients reported less anxiety and depression and better quality of life after the procedure.

Cheek thickness increased in 2 studies involving 299 and 38 patients. In the study of 299 patients, there was an increase of about 5 mm in average cheek thickness in all groups 4 years after the procedure, and the study of 38 patients reported an improvement in average cheek thickness of almost 10 mm, 5 years after the procedure.

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 aims of treatment are to improve appearance, restore fat to the areas where it has been lost, and to improve patients' satisfaction with their appearance.

Risks and possible problems

Three studies (involving 32, 267 and 18 patients) reported 61 infections and 3 possible infections between 2 months and 4 years after the

procedure. Most patients with infections or possible infections were treated with antibiotics and surgical removal of the gel. Dental work or cosmetic surgery after the procedure was commonly associated with infection in the studies of 32 and 267 patients. The study of 18 patients reported that infections in 4 patients were caused by procedures to adjust the position of the gel.

Small lumps (nodules) under the skin or hardening of the skin were found in 2 studies (involving 32 and 145 patients) up to 50 months after the procedure. Lumps were found in 8 patients in the study of 32 patients. In the study of 145 patients the lumps (in 28 out of 145 patients) and skin hardening (in 9 out of 145 patients) were not visible.

In 2 studies (involving 69 and 18 patients) there were reports of problems with the gel. In the study of 69 patients, the gel moved out of place in 9 out of 36 patients and 8 of these had surgery to remove it. In the study of 18 patients, the gel leaked into the mouth through the lining of the cheek in 1 patient, and had to be removed by surgery. These problems were reported at an average of 12 months after the procedure.

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 possible problems include blockage of a blood vessel, inflammation after the procedure, unsatisfactory appearance, and the procedure only working for a short time before further treatment is needed.

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. HealthTech 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

This document is about 'deep dermal injection of non-absorbable gel polymer for HIV-related lipoatrophy'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG300

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage to use this service.

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

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