

Transplanting a patient's own pancreatic islet cells to improve blood sugar control following pancreatectomy

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

This leaflet is about when and how transplanting a patient's own islet cells can be used in the NHS to treat people who are having an operation to remove all or part of their pancreas (known as a pancreatectomy). 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.

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 the procedure in detail – a member of your healthcare team should also give you full information and advice about this. 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 page 9.



What has NICE said?

In hospitals with special units that can isolate islet cells from the pancreas, this procedure can be offered routinely as a treatment option for people having a pancreatectomy provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

If a doctor wants to use this procedure, they should take extra steps to explain that the patient may need to take insulin in the long term. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion.

A team of specialist doctors who are experienced in the management of complex, long-term disease of the pancreas should decide which patients should have this procedure. The procedure should only be done by surgeons with experience of complicated pancreatic surgery and clinicians with experience in isolating and transplanting islet cells.

NICE has also decided that any further research or information should look at patients' quality of life, insulin dependence, diabetic control and how well the procedure works in the long term.

Other comments from NICE

The National Commissioning Group is an organisation that plans, funds and monitors NHS treatment of very rare conditions, separately from primary care trusts. It has chosen certain hospitals for isolating pancreatic islet cells, where this procedure should be performed.

This procedure may not be the only possible treatment for blood sugar control following pancreatectomy. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Transplanting a patient's own pancreatic islet cells following pancreatectomy

The medical name for this procedure is 'autologous pancreatic islet cell transplantation'. The word 'autologous' here means cells that are taken from the patient's own body.

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

Insulin is important for controlling the balance of sugar in the body. It is made in special cells in the pancreas called islet cells. Some patients with chronic pancreatitis (long-term inflammation of the pancreas) or non-cancerous tumours of the pancreas may need an operation to remove all or part of the pancreas (called total or partial pancreatectomy). Diabetes can develop in these patients as their bodies can no longer make enough insulin.

Autologous pancreatic islet cell transplantation involves the removal of the islet cells from the pancreas. It is performed at the same time as pancreatectomy. The patient is given a general anaesthetic and all or part of the pancreas removed. The islet cells are then taken from the pancreas and prepared for transplantation. They are then infused in a solution through a thin flexible tube into the portal vein, which is the vein

that carries blood and nutrients from the bowel to the liver. If the procedure is successful, the islet cells are transplanted into the liver where they start making insulin.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough in the short term for use in NHS hospitals with special units that can isolate islet cells from the pancreas. If your doctor thinks transplanting your own islet cells from your pancreas is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

Your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you, including the possibility that you may still need to take insulin in the long term. 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 leaflet, and have the opportunity to discuss it with your doctor before making your decision.

Further research and information should look at quality of life, insulin dependence, diabetic control and how well the procedure works in the long term.

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 operation?
- 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 eight studies on this procedure.

How well does the procedure work?

In a study of 64 patients who had total pancreatectomy and islet transplantation, 44 did not need to take insulin after the procedure. Eight patients produced some insulin themselves, but also needed to take additional insulin.



In a study of 48 patients, 39 were tested for diabetes after the procedure. Twenty patients did not need insulin one month after the procedure, although five of these needed insulin in the future. One patient still did not need to take insulin 10 years later.

In a study of 13 patients, 11 did not need insulin after 6 months and 5 of these patients still didn't need it 2 years after the operation. However, in a study of 40 patients, 21 patients were assessed after 6 months and only 5 of these did not need to take insulin. Three years later, 14 patients from this study were checked and all were found to have either diabetes or problems with their blood sugar control (known as impaired glucose tolerance).

One study of 45 patients reported that 18 did not need to take insulin at an average of 18 months later. Another study of 24 patients reported that 23 did not need to take insulin after islet cell transplantation; however, within 8 years of the operation 8 of these patients needed insulin.

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 were quality of life, blood sugar control, long-term insulin independence and preventing the long-term problems associated with diabetes.

Risks and possible problems

In the study of 48 patients, 2 (who had their spleens removed during the same operation) had serious bleeding caused by increased pressure in veins to the liver.

The study of 40 patients reported problems including a blood clot in the portal vein in one patient and in the spleen of another, tissue death caused by cutting off the circulation to the spleen in one patient,



bursting of the spleen requiring removal in another and formation of an abnormal passage to the spleen in one patient.

A patient in one study was found to have a condition called thrombocytopenia, which affects clotting of the blood, caused by the use of a drug called heparin in 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 clots or high blood pressure in the portal vein, tissue death caused by cutting off the circulation to the liver, liver failure, bleeding into the abdomen, leakage of bile, bursting of the spleen, problems with the proteins that control blood clotting, infection (including serious liver infection) and blockage to the lungs caused by the islet cells are all possible complications.



More information

[NHS Direct online](#) may be a good starting point for finding out more.

Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice 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. This 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 leaflet is about 'Autologous pancreatic islet cell transplantation for improved glycaemic control after pancreatectomy'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG175

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1695).

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



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