

Patient agreement to investigation or treatment

Simultaneous Kidney and Pancreas Transplantation

Authors: Cambridge Transplant Unit

Brief description:

- A kidney transplant operation has been recommended for you because either your own kidneys have already failed (currently you are having dialysis) or are failing (you are soon to start having dialysis). As a patient with diabetes the kidney transplant will be combined with a pancreas transplant performed simultaneously to provide the insulin that your own pancreas no longer provides.
- Here, we explain some of the aims, benefits, risks and alternatives to this procedure (operation/treatment). We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website: <http://www.addenbrookes.org.uk/consent>
- Remember, you can change your mind about having the procedure at any time.

For staff use:

Does the patient have any special requirements? (For example, requires an interpreter or other additional communication method)

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About simultaneous kidney and pancreas transplantation

This is a major operation involving a team of transplant surgeons working for approximately six to eight hours. If successful it will restore your kidney function and you will not need to start dialysis or continue with dialysis. Your blood sugars will be controlled for you without the need for any insulin injections or particular diet constraints.

Before your procedure

- Your Nephrologist (kidney specialist) and Transplant Surgeon will have discussed your condition with you and with other surgeons and personnel related to the National Transplant Programme. They will have decided to add your name to the Cambridge Transplant Waiting List for combined kidney and pancreas transplantation. When an appropriately matched kidney and pancreas are available, you will be contacted by phone or pager. At this time, you will be asked to report to Ward C9 at Addenbrooke's without any delay. This is because the new kidney and pancreas cannot survive outside the human body for more than a few hours.
- When you arrive, a doctor will see you on ward C9, go through your medical history again, examine you, and take some blood for urgent tests. You will then wait for the new kidney and pancreas to reach Addenbrooke's, before you are prepared and taken to the theatre for the transplant operation.
- This procedure involves the use of general anaesthesia. See below for further details about this type of anaesthesia.
- Most people who have this type of procedure will need to stay in hospital for between 10 to 21 days. Sometimes we can predict whether you will need to stay for longer than usual - your doctor will discuss this with you before you decide to have the procedure.

Prevention of Surgical Site Infection (SSI)

In order to prevent infection, hair from the area where you are being operated on may need to be removed.

Hair removal from the site of the operation up to sixty minutes before surgery reduces the risk of infection. This means that the hair removal procedure is usually carried out on the operating table. The skin is then cleaned with an appropriate skin preparation solution. This can leave a colouration to the skin which can be washed off.

You must not shave the area that is being operated on yourself; this will be carried out in the operating theatre. Shaving at home, or the night before surgery, increases the risk of infection as no matter how careful you are the skin may become irritated and this could increase the risk of infection.

It may be necessary during the procedure to shave other areas of your body if appropriate to allow equipment/machines, for example diathermy machines (used to seal blood vessels), to stick to your skin to achieve the best and safest performance.

Reference:

Department of Health. High Impact Intervention No 3: Preventing surgical site infection. Saving Lives: reducing infection, delivering clean and safe care: DH June 2005.

Who will perform my procedure?

- The kidney and pancreas transplant operation will be carried out by an appropriately experienced and trained surgical team.

During the procedure

Before your procedure, you will be given the necessary anaesthetic - see below for details of this.

- We will place several lines (tubes) into some blood vessels in your arms and neck. These give you fluids and/or blood, and help us take blood for tests and monitor your condition. In addition, a tube might be passed into your stomach through the nose to decompress (deflate) your stomach. We also place a urinary catheter into your bladder during the operation to drain the urine, which will stay in place for about five days. You may also be fed through a tube into the abdomen (jejunostomy) inserted at the time of your operation.
- A team of surgeons will first prepare the new kidney and pancreas and then carry out the transplant procedure in you. The surgeon will make a long vertical incision (cut) in your abdomen, and possibly a second curved incision on one side of your lower abdomen (tummy). The new kidney and pancreas will then be connected up to the blood vessels that take blood to your legs. We also connect the other kidney tube (ureter) to your bladder so it can produce urine as normal, and the pancreas to the bowel so that it can drain the digestive juices. Typically, this takes six to eight hours; if we encounter any difficulties, the operation might take substantially longer.
- It is common for us to remove your appendix during the course of the procedure. If you have gallstones we might also remove your gall bladder at the same time to stop you having problems after the transplant operation.

After the procedure

- After the transplant has been carried out, you will be taken either to an intensive care bed on level three, or a high-dependency bed on ward C9. Usually you are woken up from the anaesthetic on the same day. Occasionally, depending on your condition, the team might decide to keep you anaesthetised and on a breathing machine (ventilated) for a day or two in intensive care.

- After this procedure, most people will have a small, plastic tube in one of the veins of their arm. This might be attached to a bag of fluid (called a drip), which feeds your body with fluid until you are well enough to eat and drink by yourself.
- A nurse will check your pulse and blood pressure regularly to monitor your condition. When you are well enough to be moved, you will be taken to a ward.
- Sometimes, people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.
- **Eating and drinking:** Generally, you will be allowed to eat and drink on the third or fourth day after the operation. You may also be fed through a tube into the abdomen (jejunostomy) inserted at the time of your operation.
- **Getting around and about:** As soon as you are able, you will be encouraged to move around and carry out deep breathing exercises. This both reduces the chance of getting a blood clot in the leg and also helps you to avoid chest infections.
- **When you can leave hospital:** Following a simultaneous kidney and pancreas transplant, you are likely to need to stay in hospital for 10 to 21 days. You might however, need to stay longer. The actual time that you stay in hospital will depend on your general health, how quickly you recover from the procedure and your doctor's opinion.
- **When you can resume normal activities including work:** When you leave hospital, you should be able to carry out light daily activities at home. However, it might be a few months before you can return to normal active work.
- **Special measures you need to take after the procedure:** You will be given more detailed information about any special measures you need to take after the procedure. You will also be given information about things to watch out for that might be early signs of problems (for example, infection).
- **Check-ups and results:** In the period after the operation, you will be seen in the transplant outpatient clinic very regularly (twice a week to start with) to check your progress and to make sure your new kidney and pancreas are functioning well.

Intended benefits of the procedure

- Kidney transplantation offers you the possibility of either coming off dialysis or avoiding starting it. Most people who have had a kidney transplant consider they have a better quality of life and gain relief from (or avoid) several of the complications associated with dialysis.
- Pancreas transplantation offers you the possibility of coming off insulin. By controlling your diabetes it should slow, stop or even reverse some of the complications of diabetes that you experience. In the long term it might increase your chances of living longer than if you had a kidney transplant alone.
- We expect eight or nine out of ten of our transplanted kidney and pancreas transplants to work at least one year after the transplant operation; we expect five out of ten to be still working 10 years after.

Alternative procedures that are available

- It is possible to live without a kidney transplant; depending on the condition of your kidneys, you will need to continue with (or start) either haemodialysis or peritoneal dialysis to perform some of the functions of healthy kidneys. You can live without a pancreas transplant by continuing with insulin. You can have a kidney transplant without a pancreas transplant.
- Islet transplantation, where the insulin producing cells are separated from the pancreas, is currently being developed in specialized centres around the world, but is not widely available and the results have not been proven to be as good as pancreas transplantation.

Serious or frequently occurring risks

- Simultaneous kidney and pancreas transplantation is a complex procedure. There is between a 1 in 20 and 1 in 40 risk of death in the first year following the transplant operation.
- There is a small risk (1 in 20) that the blood vessels of the new kidney or pancreas will become blocked following this procedure. This will lead to failure of the kidney and/or pancreas and we will need to remove the new kidney and/or pancreas in a further operation.
- There is a chance (2 in 5) that you will require at least one further operation following the transplant. This might be to address any of a number of possible complications, including bleeding, leaking from the join with the bladder or bowel, or to take a tissue sample from the pancreas (a biopsy).
- After the operation, there is an overall one in four risk of acute rejection of the new kidney or pancreas. If this happens, we will need to give you some extra treatment with more powerful medications.
- In the longer term, you might develop chronic rejection of the new kidney or pancreas. If this happens you might need to have a further transplant procedure and/or you might need to go back on dialysis (for example, while you wait for another kidney) and/or start back on insulin.
- Most people who have had a kidney and pancreas transplant need to undergo further admissions into hospital in the subsequent months and years. These are necessary so that we can check you by using blood tests, scans, and biopsies.
- As with any other operation, complications can occur, such as wound infections, blood clot in the legs, fluid leak from drains and wound sites. These complications can often be managed with medication, rather than any further surgical procedures.
- We take every effort to screen kidney donors for infections and cancers, however, we cannot guarantee that an infection or cancer will not be transmitted from the donor to you the recipient. The risks are extremely low, and similar to the chance of catching an infection from a blood transfusion.

Drugs

It is common for some drugs, particularly the immunosuppressive drugs, to be used in combinations or for conditions for which they were not originally licensed. This is common practice in transplant units such as ours, and such use has been acknowledged by the National Institute of Health and Clinical Excellence. Any new drugs that we use will have been approved by Addenbrooke's Hospital Drug and Therapeutic Committee, or, in the case of clinical trials, by the Research Ethics Committee.

Problems with immunosuppression

- In order to protect the new 'foreign' kidney and pancreas from rejection by your immune system, you will need to take some powerful immunosuppressive medications. Although these should protect your new kidney, they also reduce your immunity and make you more susceptible to some infections, particularly viral infections.
- The potential side effects of these medicines include infections, kidney problems, diabetes, stomach upset and wound problems. There is also a higher risk of cancer in patients taking these medications.
- To reduce any side effects, the medical team will regularly monitor the medications you take and adjust them when required, based on your specific condition.
- It is very important that you follow our instructions on when and how to take your medication. If you do not follow the dosage schedule strictly (ie if you miss taking tablets), you run a significant risk of losing your kidney and/or pancreas without the prospect of a new one.

Please remember that the Transplant Unit has recommended the kidney and pancreas transplant procedure to you because the team feels that the benefits will greatly outweigh the risks for you.

Information and support

If you have any anxieties or questions, please feel free to ask any member of the staff. Further information can be obtained from the Transplant Co-ordinators who can be reached through the Addenbrooke's Switchboard on 01223 216536 or from the Addenbrooke's website www.addenbrookes.org.uk or www.cambridgetransplant.org.uk

Your anaesthesia

General Anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation.

Before your operation

- Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic. He or she will need to understand about your general health, any medication that you are taking and any past health problems that you have had. Your anaesthetist will want to know whether or not you are a smoker, whether you have had any abnormal reactions to any of the drugs or if you have any allergies. They will also want to know about your teeth, whether you wear dentures, have caps or a plate.
- Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period.
- Your anaesthetist may examine your heart and lungs and may also prescribe medication that you will be given shortly before your operation, the pre-medication or 'pre-med'.
- **Pre-medication** is the name given to medication (drugs) given to you some hours before your operation. These drugs may be given as tablets, injections or liquids (to children). They relax you and may send you to sleep. They are not always given.
- Do not worry if you do not have a pre-med, your anaesthetist has to take many factors into account in making this decision and will take account of your views on the topic if possible. Do not be worried about your anaesthetic. When your anaesthetist visits you before your operation, this is the time to ask all the questions that you may have, so that you can forget your fears and worries.
- Before your operation you will usually be changed into a gown and wheeled in a bed to the operating suite into an anaesthetic room. This is an ante-room outside the theatre.
- The anaesthetist, his or her assistant and nurses are likely to be present.
- An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe. It is common practice nowadays to allow a parent into the anaesthetic room with children: as the child goes unconscious, the parent will usually be asked to leave.

During your operation

- While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond.
- Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing.
- He or she will also constantly watch your need for fluid or blood replacement. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

- After your operation your anaesthetist continues to monitor your condition carefully.
- You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you.
- Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness.
- You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require.
- You will be given medication for any pain that you might feel, and systems, such as Patient Controlled Analgesia (PCA), may be set up to continue pain control on the ward. (This is a pump to deliver pain relief).
- You are likely to feel drowsy and sleepy at this stage.
- Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery.
- During this time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams.
- Once you are fully awake you will be returned to the ward.
- If the team decide to keep you anaesthetised and on the breathing machine (ventilator) you will be looked after in the intensive care unit.

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on:

- whether you have any other illness

- personal factors (such as smoking or being overweight) or surgery which is complicated
- if the anaesthetic time is long or the operation is done in an emergency rather than a planned procedure

Please discuss any pre-existing medical condition with your anaesthetist.

Very common and common side effects (1 in 10 or 1 in 100 people)

Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and soreness, confusion or memory loss.

Uncommon side effects and complications (1 in 1000 people)

Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).

Rare or very rare complications (1 in 10,000 or 1 in 100,000)

Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

Help with this leaflet:



If you would like this information in another language, large print or audio format, please ask the department to contact

Patient Information: 01223 216032 or

patient.information@addenbrookes.nhs.uk



Document history

Authors	Transplant Surgery
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Consent Form (Adults)

Patient agreement to
investigation or treatment

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Responsible health professional/job title

Special requirements.....
(For example, other language/other communication method)

Name of proposed procedure or course of treatment

Simultaneous kidney and pancreas transplantation

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- **The intended benefits of the procedure:**
- Either coming off dialysis or avoiding starting it.
- Possibility of coming off insulin. Controlling your diabetes should slow, stop or even reverse some of the complications of diabetes. Might increase chances of living longer than if you had a kidney transplant alone.
- We expect eight or nine out of ten of our transplanted kidney and pancreas transplants to work at least one year after the transplant operation; we expect five out of ten to be still working 10 years after.
- **Any serious or frequently occurring risks including those specific to the patient:**
- Between a 1 in 20 and 1 in 40 risk of death in the first year following the transplant operation.
- 1 in 20 risk that the blood vessels of the new kidney or pancreas will become blocked following procedure leading to failure of the kidney and/or pancreas - we will need to remove the new kidney and/or pancreas.
- There is a chance (2 in 5) that you will require at least one further operation following the transplant.
- After the operation, there is an overall one in four risk of acute rejection of the new kidney or pancreas.
- Chronic rejection of the new kidney or pancreas. If this happens you might need to have a further transplant procedure and/or you might need to go back on dialysis and/or start back on insulin.
- Wound infections, blood clot in the legs, fluid leak from drains and wound sites.
- We take every effort to screen kidney donors for infections and cancers, however, we cannot guarantee that an infection or cancer will not be transmitted from the donor to you the recipient.
- Any extra procedures that might become necessary during the procedure

Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

- The following information leaflet has been provided: Version/Date/Ref: CF170 4, August 2011

This procedure will involve:

General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature:Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature..... Date:

Name (PRINT):

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will (eg Jehovah's Witness form)

Statement of patient

For staff use only: Surname: First names: Date of birth: Hospital no: Male/Female: (Use hospital identification label)

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)
I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.
I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.
I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

.....
I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.
I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.
I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. Yes No

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** If you wish to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature: **Date:**

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature: **Date:**

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature **Date:**

Name (PRINT): **Job Title:**

Copy accepted by patient: yes / no (please circle)