

6. Missed lesions:

No test is perfect, including EUS, and in a small number of cases, a significant pathology can be missed, even in experienced hands.

7. Rarely

EUS or its complications can be life threatening.

8. Failure:

Sometimes, the procedure may be incomplete, which can be influenced by a number of factors. If this is the case, other procedures may also be required. (see the alternatives' section)

What are the alternatives to a EUS +/-FNA?

At present, EUS is primarily (though not always) a diagnostic procedure. Other kinds of X rays such as an MRCP can be used to obtain similar information, but cannot perform a biopsy. Alternatives to EUS FNA include a procedure known as a CT guided biopsy, where the area of interest is accessed through the abdominal wall, or surgery (either open surgery or laparoscopic 'keyhole' surgery). These procedures also carry significant risks.

Other important points to note:

As the Mater is a University Teaching Hospital, a person other than the consultant, such as a registrar (senior trainee) or advanced nurse practitioner (ANP), may perform the procedure.

That person will be under the supervision of a consultant. During the procedure, video footage and photographs may be taken- these will form part of the medical record and assist the doctor in providing medical treatment.

These images may also be used at a later date for audit or research purposes, but will be anonymous.

Giving your consent

I,
have read the information provided outlining the procedure itself, the associated risks and complications, the benefits and alternatives to a EUS+/-FNA.

I have been given the opportunity to ask questions, and they have been answered to my satisfaction.

I understand that I have the right to withdraw my consent at any time, even after this form has been signed.

I understand that in the event of an emergency, the medical staff will carry out any medically necessary interventions. These may include, but are not limited to surgery, radiologic procedures, anaesthesia, blood transfusion.

Every effort will be made to include me in this decision making process where possible.

I consent to undergo the procedure EUS+/-FNA

Signature of patient/guardian:

.....

Date:

.....
Day / Month / Year

Signature of nurse/doctor:

.....

.....
Day / Month / Year

Signature of Endoscopist:

.....

.....
Day / Month / Year

Interpreter:

I confirm that I have given a sight translation of the consent form in the language and assisted in the translation of verbal and written information given to the patient by the doctor/health care provider.

Full Name: *Block Capitals*

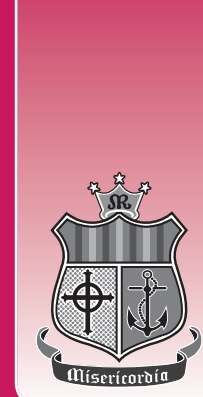
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Signature:

Date:

.....

.....
Day / Month / Year



Mater Misericordiae University Hospital

Consent for an ENDOSCOPIC ULTRASOUND FINE NEEDLE ASPIRATE (EUS +/- FNA)

PLEASE READ THIS LEAFLET CAREFULLY AND
CONTACT US **BEFORE** YOUR PROCEDURE DATE IF
YOU HAVE QUESTIONS OR CONCERNS

GI unit

Phone: (01) 803 2366 Email: giunit@mater.ie
www.mater.ie/services/gastrointestinalunit

What is EUS?

EUS is a procedure in which the doctor passes a thin, flexible tube through the mouth, down the oesophagus (gullet) to the stomach and first part of the intestine (duodenum). From those positions, the doctor can examine the ducts of the liver and pancreas, the pancreas gland, the walls of the intestine, or other structures outside that area, including in the chest. This procedure is used to diagnose a wide range of conditions, from bile duct stones to cancer. If a fine needle aspirate is taken during the procedure, biopsies or cytology samples (small pieces of tissue) will be obtained. It is necessary to retain this tissue in order to examine it fully. Please see the accompanying letter for information on how to prepare for your procedure.

What will happen during the procedure?

You will be checked in by the administrator on arrival at the GI Unit and thereafter, a nurse will call you to complete the medical checks and place an IV line in the arm. **Please bring a list of your medications with you.** If an FNA is to be performed, the nurse will draw blood to ensure it is safe to proceed. It is necessary to wait for this blood result prior to starting the procedure. Please bring a list of your medications with you. If you are travelling from another hospital for a day case procedure, the staff will send the relevant information with you. However it is important that you read this information before leaving your own hospital, to give you time to ask questions or raise concerns if you have any. It will also give you an opportunity to discuss the procedure with your family.

Tick here to indicate you received the information in your own hospital and have had time to consider it and discuss with relevant parties.

In the endoscopy room, the nurse will go through the safety checks again. You will be given local anaesthetic spray to the throat. You will be asked to lie on your left side. A mouth guard, which protects the teeth, will be placed in the mouth. Sedation is given at this stage, along with oxygen through the nose. Your pulse, oxygen levels and blood pressure will be recorded throughout the procedure. You will be relaxed and comfortable, which is the desired result of the sedative (you will not be 'knocked out' as you would for an operation). The EUS scope will be passed

through the mouthguard and down the gullet. It does not interfere with normal breathing. You may regurgitate some air (belch) during the procedure. Once the doctor has obtained the necessary images, he/she will decide if an FNA is needed. If this is the case, a different scope is passed through the mouth which allows a small needle to take a sample from the wall of the gut or an area outside it.

Once the procedure is finished, you will be brought to the recovery area and monitored until you are fully recovered from the sedative. There may be restrictions on eating and drinking after the test depending on what has been done during the procedure.

Once you have recovered from the sedative, an ambulance will bring you back to your own hospital, or you will return to the ward within the hospital, or your family member or friend can collect you. You will be given as much information as possible about the results before you leave, a copy of the report for your GP/ referring doctor and instructions to follow after the procedure.

The sedation will impair your ability to perform a number of tasks for 24 hours, so it is important to follow these instructions carefully.

Risks of EUS

The risk of a serious complication as a result of EUS is very small. Approximately **one person in every 1000** undergoing a diagnostic EUS will have a significant problem. **The risk increases if an FNA is performed** (but is still less than 1 in 100 procedures) or if the patient has certain other medical problems. Complications can be related to

1. Medication:

It is rare to encounter this problem. A person may suffer from phlebitis (inflammation of the vein) at the site of the IV line. Additionally, the injected sedatives may cause problems with the heart or lungs, particularly if there is an underlying problem in those areas, or in the elderly, or in an emergency situation. (between 2 and 5 people per 1000 procedures could develop sedation related heart or lung problems). For this reason, we must take care with those medications and avoid 'oversedation'. Rarely, a reaction can occur with the local anaesthetic used to numb the throat.

Very rarely, a life threatening allergic reaction known as 'anaphylaxis' could occur following administration of medication.

2. Pancreatitis:

This is swelling and inflammation of the pancreas, and can occur in **1 of every 100** people undergoing EUS FNA of the pancreas. It causes abdominal pain, for which IV fluids, pain relief and a hospital stay will be required. In most cases, it settles down after 24-48 hours.

In some cases it can be severe and need further treatment, including surgery or an intensive care unit stay.

3. Bleeding:

This occurs in less than **2 in every 1000** cases. It usually occurs at the site of the fine needle aspirate. The risk may be increased by the presence of a bleeding condition, or if a patient is taking blood thinners, so your blood tests will be checked to ensure it is safe to proceed, and blood thinning medication will usually be put 'on hold' to lessen any bleeding risk.

4. Perforation:

This is a tear or hole in the lining of the oesophagus, stomach or duodenum. This occurs in less than **1 in 1000 cases**. Often it will settle with 'conservative measures' – intravenous fluids, pain relief, antibiotics and drainage of the stomach by a nasal tube. However, in other cases, surgery or other techniques may be required.

5. Infection:

This occurs in approximately **2 in 100** patients undergoing EUS FNA of a cyst. Antibiotics are given at the time of the procedure, and for several days after the procedure, to minimise this risk.

The risk of aspiration (overflow of stomach contents into the lungs) is small but is influenced by a number of factors. It is crucial that the 'nil by mouth' pre-procedure instruction is followed for this reason.

It is also important to avoid oversedation as this can be associated with aspiration pneumonia. In certain individuals, bacteremia (infection of the blood) can occur as a result of EUS FNA – this is usually treated with antibiotics.

