

Patient agreement to investigation or treatment

Amniocentesis

Authors: Fetal Medicine Unit – Rosie Hospital

Brief description:

- This test is not offered as a matter of routine. It is used to detect Down’s syndrome and specific genetic disorders. There is no evidence that the procedure itself harms the baby as the test is carried out under ultrasound guidance, but the test is most safely performed after 15 weeks of pregnancy.
- 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 this information in another format or language or would like help completing the form, please ask a member of our staff.
- **Let us know:** Please let us know if we need to cancel any appointments for any reason (including illness) so your ‘slot’ can be used by others. Direct dial telephone to cancel an appointment in the Fetal Medicine Unit: 01223 216185 (or switchboard 01223 245151 and extension: 2185.

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 amniocentesis

Who should consider amniocentesis?

The final decision about having any test in pregnancy is yours, but the following women may want to consider amniocentesis:

- Women with a high-risk result from a nuchal translucency scan or triple test designed to find out the risk of having a baby with Down's syndrome.
- Women who have a potential problem found on the ultrasound scan, which may suggest a chromosomal abnormality.
- Women who have had a pregnancy or a child affected by a genetic condition that can be tested for by an amniocentesis.
- Couples who have had a baby with Down's syndrome or those who have had a family history of genetic disorders, including some rare inherited diseases that can be tested for by amniocentesis.
- Women who have missed the screening tests for Down's syndrome, or request invasive testing for their own reasons.
- The chance of having a baby with Down's syndrome by age is:
 - 25 1 in 1500
 - 30 1 in 910
 - 35 1 in 380
 - 38 1 in 190
 - 40 1 in 110
 - 45 1 in 30

What are the problems associated with amniocentesis?

Amniocentesis has now been available for a number of years and in Britain over 15,000 women have the test performed every year. We therefore know a lot about its safety and accuracy. We know that the test can sometimes cause a miscarriage and approximately 1 in every 100 women, who have the test, will miscarry as a result of the procedure. There is no evidence that the procedure itself harms your baby as the test is carried out under ultrasound guidance.

Is the amniocentesis test reliable?

No test is absolutely perfect, but the chromosome test for Down's syndrome is very reliable. It fails to give a clear result in less than 1 in 1000 cases. If you are having the amniocentesis for other genetic disorders, you should discuss the accuracy of the test with your genetic doctor or counsellor.

Will the test tell me about anything other than Down's syndrome?

Although you may be having an amniocentesis to detect Down's syndrome, the test may occasionally detect problems with the other chromosomes.

If the results show anything abnormal you will be told what the abnormality is and how this will affect your baby.

How is amniocentesis performed?

The test involves taking a small amount of the amniotic fluid (water) that surrounds the baby in the womb. This fluid contains cells from the baby that are tested in the laboratory.

Before the test is performed, an ultrasound scan is carried out to check your dates and the position of both the baby and the placenta (afterbirth). You will not need a full bladder for this scan.

The skin over the abdomen is cleaned and a fine needle is then passed into the womb. A sample of the fluid that surrounds the baby is removed and sent to the laboratory. The position of both the baby and the needle are monitored throughout the procedure by ultrasound.

Is amniocentesis painful?

Most women say afterwards that the test is uncomfortable rather than painful and feels similar to period pain. Generally, women say that the thought of it is worse than the actual test.

What happens after the amniocentesis test?

You will probably be at the hospital for about half an hour, but the test itself just takes a few minutes.

If your blood group is Rhesus negative, you will be given an injection following the procedure to prevent the formation of antibodies in your blood, which may otherwise affect future pregnancies.

We encourage you to bring a companion with you for support during and after the test. It is a good idea to take things easy for a couple of days, although this will not affect your risk of miscarriage.

The "period pain" feeling may persist for 24 to 48 hours. This is not unusual and should settle after rest and Paracetamol, which is safe to take in pregnancy. If you have excessive pain, are leaking any fluid, bleeding or develop a high temperature, please contact your local labour ward for advice.

Benefits of the procedure

It is the only way to know whether baby's chromosomes are normal or not.

Alternative procedures that are available

We will discuss with you whether an alternative procedure such as CVS (chorion villus sampling) would be appropriate.

When do you get the results?

The chromosome test involves growing cells in the laboratory using a rapid method called a QF-PCR (Quantitative Fluorescent Polymerase Chain Reaction) test. These tests will assess 3 of the possible 23 pairs of chromosomes in the baby. The chromosomes that will be assessed will be chromosome 21, 18 and 13, as too many or too few of these chromosomes in an individual are the most common cause of fetal abnormality in the population namely trisomy 21 (Down's syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau's syndrome).

These tests do not detect other chromosomal rearrangements (a structural change in a chromosome) or abnormalities of the sex chromosomes. If clinically indicated, sex chromosome tests and full karyotype may be undertaken.

This test usually takes about three working days. In certain situations a further test will check all chromosomes of the baby and this result will take about two weeks. If the chromosomes are normal, we will send you a written report by post.

If you are having an invasive test because of ultrasound anomaly, genetic conditions or history then the rapid QF-PCR **and** full karyotype will be performed. The rapid test result will be available within three working days and the full karyotype will be available at 10-14 working days.

If you are having an invasive test due to an increased risk from Down's screening then only the rapid QF-PCR test would be performed. If you wish to have the full karyotype then an additional charge would be made to cover the laboratory expenses involved in this.

As the full karyotype is not performed, it is anticipated a small number of babies will be affected by clinically important chromosomal abnormalities which will not be detected by QF-PCR.

The guideline was developed on the recommendation of the National Screening Committee.

What if the results are abnormal?

If a chromosome problem is detected, you will usually be contacted by either the Fetal Medicine Unit or your own referring hospital. You will usually be contacted by telephone and given an opportunity to discuss the findings. You will be told what the abnormality is and how this could affect your baby. You will have the chance to discuss the results fully before making any decisions.

You will be contacted in one of three ways:

1. By a genetics counsellor by prior arrangement,
2. By Fetal Medicine Unit at the Rosie Hospital,
3. Or by your own referring Hospital.

HIV infection

We would encourage women who are HIV positive to discuss invasive testing with their specialist midwife or doctor to obtain further information. This is because there is a small risk that the HIV virus can be passed on to the developing baby during the procedure.

Outcome of pregnancy

Outcome information is very important to us as this enables us to audit and improve our service. Following your appointment with us, you will be given an outcome form and an addressed envelope, which we would be very grateful if you would complete and return to us.

Contacts

If you have any questions about amniocentesis please telephone the Fetal Medicine Unit at the Rosie on 01223 216185. We can arrange for a fetal medicine midwife to talk to you if you wish. We recognise that everyone will have their own particular questions and concerns. The midwife or doctor will usually be able to answer any questions you may have before you have your test.



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

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Consent form 1

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

Amniocentesis

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: how it will be performed

- The intended benefits of the procedure: It is the only way to know whether baby's chromosomes are normal or not.
- Any serious or frequently occurring risks from the procedures including those specific to the patient: the test can sometimes cause a miscarriage in approximately 1 in every 100 women
- Any extra procedures that might become necessary during the procedure
- 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: Amniocentesis
- Version/Date/Ref: 4/May 2011/CF238

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

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

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

Statement of patient

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 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 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:**