NHS

Royal Papworth Hospital

NHS Foundation Trust

Ajmaline challenge

A patient's guide and consent form

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Why have I been offered an ajmaline challenge?

This is a specialised test carried out to look for a rare heart rhythm condition called brugada syndrome, this condition can be inherited and in some cases can cause dangerous heart rhythms and in rare cases cause sudden death.

Your doctor may suspect that you have brugada syndrome if:

- A member of your family is known to have a heart rhythm disturbance.
- You have been found to have some changes on your resting ECG (heart tracing)
- You have suffered unexplained blackouts, dizzy spells or heart rhythm disturbances.
- A member of your family suffered an unexplained sudden death.

If you are unsure of the reason you have been asked to have this test, please ask your cardiologist or call the inherited cardiac conditions nurses on 01223 638947 to answer any questions.

What is brugada syndrome?

Brugada syndrome is an inherited heart rhythm condition which affects the electrical activity in the heart muscle cells, without affecting the hearts structure.

Sometimes it is called an ion channelopathy. An ion is a chemical substance such as sodium or potassium which forms the basis of the movement of the electricity through the heart muscle

An ion channel is the route that the ions take in and out of the heart muscle, they regulate the flow of electrical charge.

There are several different types of inherited heart rhythm conditions this booklet focuses specifically on brugada syndrome.

Brugada syndrome is usually inherited from your parents, although sometimes can occur in one family member.

How is the condition inherited?

Brugada syndrome occurs when there is a fault in one of the genes which determines how the heart muscle cells work, this can cause the electrical function of the heart to become abnormal.

The gene fault is passed from one generation to the next by what is known as an autosomal dominant inheritance pattern.

This means that the children of someone with brugada syndrome each have a 50% (or one in two) chance of inheriting the faulty gene.

The gene fault responsible is inherited by both men and women and doesn't skip a generation.

Most people who have inherited the gene fault do not have any symptoms so it can sometimes be difficult to spot the inheritance pattern in a family.

Brugada syndrome is not fully understood and not all the genes responsible have been identified, therefore it is not always possible to offer genetic testing.

What problems can brugada syndrome cause?

The majority of people who have brugada syndrome do not experience any heart rhythm problems and feel perfectly well. However, some patients may be at risk of developing fast heart rhythms without any warning. The fast heart rhythms can cause the heart muscle cells to contract so quickly and chaotically that the heart is no longer able to pump blood around the body effectively.

This can result in a temporary blackout or, very rarely, sudden death.

What are the benefits of having an ajmaline challenge?

An ajmaline challenge can help to determine if you have inherited brugada syndrome. This will help your cardiologist to provide advice about your risk of developing heart rhythm disturbances.

You will then be able to discuss the treatment options for you and possibly other family members.

What are the risks of having an ajmaline challenge?

Complications from a correctly performed ajmaline challenge are extremely rare.

An ajmaline challenge is usually performed in a specialist cardiac centre where doctors and nurses experienced in performing the test and correctly interpreting the ECGs are available.

These rare complications include:

- A heart rhythm disturbance, this may need to be treated with medication or on very rare occasions may require defibrillation to shock the heart back into a normal rhythm.
- An allergic reaction to the drug but this is rare.
- If you are found to have brugada syndrome this can have implications for life and health insurance and employment.

Is there any special preparation?

- The risks will be discussed with you before you decide to have the ajmaline challenge. You will have the opportunity to ask questions and when you feel you understand the risks and benefits, you will be asked to sign a consent form stating that you understand the procedure. We recommend that you read this leaflet thoroughly and make a note of anything you would like to ask.
- You must not have anything to eat or drink after 6am on the day of the test.

What happens on the day of the ajmaline challenge?

- The test is done on the day ward at Royal Papworth Hospital, you may need to be there for up to four hours.
- The drug used is called ajmaline, this is a sodium channel blocker that can unmask signs of brugada on your ECG.
- Ajmaline is an unlicensed medicine, this means it has not been given a product licence or marketing authorisation by the Medicines and Healthcare Products Regulatory Agency, however it can be supplied specifically for the ajmaline challenge.
- On arrival the test will be explained by a doctor or specialist nurse and you will be asked to sign a consent form to confirm that you understand the benefits and risks of the test and the possible implications of the result.
- You will be weighed, your blood pressure and an ECG will be recorded and a blood sample taken to test for potassium levels. Potassium can affect the heart rhythm so we check this is within the normal range. A small tube called a cannula will be inserted into a vein in your arm which is used to deliver the ajmaline.
- You will be connected you to a continuous heart monitor, this will also allow ECGs to be recorded at intervals during the test. These monitor the electrical activity in your heart during and after the test.
- The ajmaline is delivered via the cannula.
- You will be closely monitored throughout the test.
- The test normally takes approximately 15 minutes.
- Some people experience a metallic taste or a warm flush during the test.
- You need to stay in the hospital for a minimum of 30 minutes and sometimes up to four hours after the drug challenge has finished or until any changes on your ECG return to normal.

How do I get the results of my drug provocation challenge?

The person performing the test will discuss the result with your cardiologist,you will also have the opportunity to discuss the result with a cardiologist or specialist nurse before you leave hospital.

They will also discuss screening of other family members if required. You will be given a letter summarising your test results and any future treatment. This will also be copied to your GP.

Who can I speak to if I would like more information or have any questions?

Please contact the Inherited cardiac conditions /arrhythmia specialist nurses helpline at Royal Papworth Hospital on 01223 638947. Please contact us during the hours of Monday to Friday 09:00 - 17:00.

Further information can also be found on the brugada website:

brugadadrugs.org

British Heart Foundation (BHF)
Tel: 0300 4568383
bhf.org.uk

Sudden Arrhythmic Death Syndrome (SADS UK)
Tel: 01277 811215
sadsuk.org

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

PIC 24: patient agreement to PI 24 - Ajmaline challenge

Intended procedure/surgery

_____

_____

Statement of healthcare professional

(To be filled in by healthcare professional with appropriate knowledge of proposed procedure, as specified in consent policy).

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

For the procedure the patient will lie on a bed in the ward and be connected to a heart monitor and an ECG machine to record your heart rhythm during the test. The drug will be given through a small tube in your arm directly into a vein. The test is complete when all the drug is given or changes to your heart rhythm are seen.

The intended benefits: To help diagnose a condition called Brugada Syndrome. If you have brugada syndrome, we can offer advice on prevention or treatment of abnormal heart rhythms. A positive result will be used alongside other features to determine if you have the condition.

Significant, unavoidable or frequently occurring risks:

Drug provocation challenge is a safe test and complications are rare but include:

- Allergic reaction to the drug
- Heart rhythm disturbances less than 1% risk

Any extra procedures, which may become necessary during the procedure:

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The following leaflets have been provided:

☐ Ajmaline challenge

☐ British Heart Foundation inherited heart conditions – heart rhythm disturbances

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

Healthcare professional

Signed: ……..……..……..…….....

Date: ……..……

Name (PRINT): ……..……

Job title: ……..……

Contact details

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Statement of patient

Please read the patient information and this form carefully. If the treatment has been planned in advance, you should already have your own copy of which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

Yes	No	
☐	☐	**I agree** to the procedure or course of treatment described on this form and have read this information leaflet on ajmaline challenge (PI 24) and had the opportunity to ask questions.
☐	☐	**I agree** to the use of photography for the purpose of diagnosis and treatment and I agree to photographs being used for medical teaching and education.

- **I understand** what the procedure is and I know why it is being done, including the risks and benefits.

Please affix patient label or complete details below.

Full name:

Hospital number:

NHS number:

DOB:

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- **I understand** that any tissue removed as part of the procedure or treatment may be used for diagnosis, stored or disposed of as appropriate and in a manner regulated by appropriate, ethical, legal and professional standards.
- **I understand** that any procedure in addition to those described on this form will be carried out only if necessary to save my life or to prevent serious harm to my health.
- I have listed below any procedures **which I do not wish to be carried out** without further discussion:

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I have been told in the past by Public Health that I am at increased risk of CJD (Creutzfeldt Jakob disease) or vCJD (variant Creutzfeldt Jacob disease).

☐ Yes ☐ No

(Where patient indicates 'yes' health professional to refer to Trust CJD procedure DN092)

Statement of interpreter (where appropriate)

If an interpreter was present to support this consent, please state the name and number of the interpreter present:

Date: ……

Interpreter's number:……

Name (PRINT): ……

Interpreter PIN:……

If a telephone / video service has been used, please document the name of the interpreter and company below

.....

.....

Patient

Patient 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 they have no further questions and wish the procedure to go ahead.

Signed: ……

Date: ……

Name (PRINT): ……

Job title: ……

Important notes (tick if applicable).

☐ Patient has advance decision to refuse treatment

☐ Patient has withdrawn consent (ask patient to sign/date here)

Patient signature: ……

Date: ……

Name (PRINT): ……

Please use and attach Consent form C for a young person who is not Gillick competent.

Royal Papworth Hospital NHS Foundation Trust

A member of Cambridge University Health Partners

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Alternative versions of this leaflet

Large print copies and alternative language versions of this leaflet can be made available on request.

View a digital version of this leaflet by scanning the QR code.

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