Patient information and consent to Cyanoacrylate Glue Closure for Varicose Veins

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.

- Please read this information carefully, you and your health professional will sign it to document your consent.

- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.

- Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Simple painkillers such as paracetamol and ibuprofen may be required after surgery. Simple bowel medication such as senna and lactulose may be required after surgery. It is suggested that you discuss with your pharmacist and have a seven day supply of these medications at home to take as you need according to the instructions.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment.

- Please call the Vascular Nurse Specialists on telephone number 01223 596382 if you have any questions or concerns about this procedure or your appointment.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know

Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.
About Cyanoacrylate Glue Closure for Varicose Veins

Cyanoacrylate glue closure is a minimally invasive treatment for varicose veins. Cyanoacrylate glue (a special type of “superglue”) is used to seal off the main faulty veins (veins with leaky valves) in the leg. The procedure has the same effect as “stripping” the vein in a surgical operation, or closing veins by endothermal ablation (laser or radiofrequency heat treatment), but it avoids the surgical incisions needed for stripping and the multiple injections of anaesthetic fluid required for endothermal ablation.

The procedure is performed using a small amount of local anaesthetic and you will be able to go home on the day, straight after the treatment.

Intended benefits

Cyanoacrylate glue closure is intended to seal off the main faulty veins in the leg, with the aim of improving your symptoms / quality of life and reducing the risks of complications from your varicose veins (such as eczema, discolouration of the skin and ulcers). For some patients, cyanoacrylate glue treatment may have specific advantages over other treatments, including less pain (as there are fewer injections needed), less bruising and the avoidance of compression bandaging or stockings after treatment (for most patients). However, like any other treatment you should understand the benefits and the risks of the glue procedure before you agree to undergo treatment.

Cyanoacrylate glue treatment is quite new. NICE (the National Institute for Health and Care Excellence) has produced guidance on its use (Interventional Procedures Guidance 526 – July 2015). This describes evidence of good effectiveness and no serious side effects, but it recommends that more evidence is needed before glue can be used in a “routine” way. In particular, NICE recommends that surgeons using glue should be able to offer a choice of procedures, and should have had special training in the procedure. NICE also specifies that the results of glue treatment should be checked, so we will arrange a clinic follow-up appointment for you.

Who will perform my procedure?

This procedure will be performed by a consultant vascular surgeon or senior vascular trainee under direct consultant supervision.

Before your procedure

Most patients who are suitable for cyanoacrylate glue closure will be assessed by a consultant in the vascular clinic. They will undergo an ultrasound scan of their veins to see if they are suitable for this treatment. You will not need to attend the hospital again until the day of your procedure. Usually, there is no need to stop or change your usual medication before the procedure. However, if you are taking hormone replacement therapy (HRT) or the contraceptive pill, then please inform the medical team as these medicines may need to be stopped before the treatment. We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring all your medications and any packaging (if available) with you.
Please tell the ward staff about all of the medicines you use. If you wish to take your medication yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

This procedure involves the use of anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

Most people who have this type of procedure will be able to go home the same day.

**During the Cyanoacrylate Glue Closure for Varicose Veins**

An ultrasound scan will be used to assess the veins that require treatment. A local anaesthetic injection will freeze the skin and a small flexible wire will be passed into the vein. A fine tube is passed over this wire into the vein and the glue is carefully injected into this tube. The position will be carefully checked using the ultrasound scanner. Small doses of glue are injected along the length of the vein (through the fine tube). After the injections, the surgeon will press on the skin for short periods to help seal off the vein.

Occasionally prominent varicose veins will be marked by the surgeon prior to the procedure and may be removed through small incisions (phlebectomies). This is not routine as in many cases, these veins will shrink away after treatment of the main faulty vein. Any small incisions are closed with glue or steristrips which can be removed after five days. For most patients, there is no need for a bandage or compression stockings after glue treatment.

**After the Cyanoacrylate Glue Closure for Varicose Veins**

**Getting about after the procedure:**

After cyanoacrylate glue closure, you will be able to walk almost immediately and go home. You can walk as much as you like, as soon as you like. You will not cause any damage to your leg by walking. You should not drive home. If you are travelling for more than one hour from the hospital you should sit on the back seat with your leg(s) up. Stop every hour and walk around for five minutes.

**If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.**

**Eating and drinking.** After this procedure, you can usually eat and drink immediately, providing you are feeling well.

**Getting about immediately after the procedure.** We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. If you have any mobility problems, we can arrange nursing or physiotherapy help.
Leaving hospital. Generally most people who have had this operation will be able to leave hospital the same day. However, the actual time that you stay in hospital will depend on your general health, how quickly you are recovering from the procedure and your doctor’s opinion.

Resuming normal activities including work. Normal activities, including work, can be resumed as soon as you like (the next day for most jobs), although contact sports, heavy exercise and swimming should be avoided for one to two weeks.

Special measures after the procedure: The risk of DVT during long air flights or other long journeys (car, train or coach) in cramped seating is very low, but the normal advice is to avoid air travel for six weeks before or after any varicose vein treatment. We will also give you information about things to watch out for that might be early signs of problems (e.g. infection).

Check-ups and results: Before you leave hospital, we will organise an appointment for an outpatient clinic to assess your recovery. At this time, we can check your progress and discuss any further treatment.

Significant, unavoidable or frequently occurring risks of this procedure

- There is a small chance the vein may not be completely sealed after the glue procedure (this occurs in less than 5% of patients).

- As with any surgical procedure there is a small risk of blood clots forming in the main leg veins (DVT). However, this is less common after cyanoacrylate glue closure than conventional varicose vein surgery. DVT is less likely to occur if you start moving your legs and walking frequently soon after treatment.

- Some patients have noticed redness and discomfort over the treated vein within the first one to two weeks of treatment. This may be some inflammation in the treated vein (phlebitis), which will settle. If you get pain or tenderness then take an anti-inflammatory painkiller (e.g. ibuprofen) and/or paracetamol. This is not an infection and does not need antibiotics.

- Allergic reactions are rare but can happen as a result of glue. Relatively minor skin reactions (like ‘hives’) have been described, but as with any injection, more serious allergy is a rare possibility.

- If any additional treatments (such as phlebectomy or ultrasound guided foam sclerotherapy) are performed at the same time as the glue procedure, then other side effects such as bruising, skin discoloration or tender lumps may occur.

- Some people develop a few new varicose veins over the years after any of the varicose vein treatments. Varicose veins may simply re-grow in the areas which have been dealt with, or they may develop in a different system of veins which was normal at the time of treatment. If veins develop again they can be treated.
Alternative procedures that are available

Varicose veins are a common condition. There are several alternative treatments available for varicose veins (listed below). Your doctor will discuss the options with you and where possible, offer the most appropriate option for your specific situation.

- Compression stockings and skin care.
- Conventional varicose vein surgery: this requires a general anaesthetic and often causes more bruising and discomfort and requires larger surgical incisions than minimally invasive methods.
- Radiofrequency ablation: this is a keyhole procedure where the faulty vein can be heated and destroyed, to seal it closed. Not all veins are suitable.
- Ultrasound guided foam sclerotherapy: This is also a minimally invasive procedure which is useful for some tortuous veins, or for patients with ulcers.

Information and support

www.vascular.society.org.uk or www.circulationfoundation.org.uk

Anaesthesia

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. The vast majority of cyanoacrylate glue procedures are performed using local anaesthesia only.

Local anaesthesia

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted. Some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.

Most people will feel fine after their cyanoacrylate glue procedure.
Information about important questions on the consent form

1  Creutzfeldt Jakob Disease (‘CJD’)

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2  Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment; they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3  Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4  Use of Tissue

As a leading biomedical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
Privacy & dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.information@addenbrookes.nhs.uk.

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history

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Version number/Ref: 1/100609
### Consent Form

**Cyanoacrylate Glue Closure for Varicose Veins**

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<th>A</th>
<th>Patient’s side</th>
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**Consultant or other health professional responsible for your care**

Name and job title:

- [ ] Any special needs of the patient (e.g. help with communication)?

**Please use ‘Procedure completed’ stamp here on completion:**

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**B Statement of health professional (details of treatment, risks and benefits)**

1. I confirm I am 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:

   a) the intended benefits of the procedure (please state)
   - Reduce symptoms
   - Reduce risk of complications of venous disease (such as ulcers, skin damage, bleeding or phlebitis)

   b) the possible risks involved. Addenbrooke’s always ensures any risks are minimised. However, all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient.

   - Infection, bruising, deep vein thrombosis (DVT) - <1%. Recurrence of varicose veins. Phlebitis or redness over treated vein. Need for further treatment. Allergy (rare). Access site granuloma (skin lump where fibre is inserted in the skin)

   c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
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1. Any extra procedures that might become necessary during the procedure such as:
   - Blood transfusion
   - Other procedure (please state)

2. The following information leaflet has been provided:
   Cyanoacrylate Glue Closure for Varicose Veins

Version, reference and date: V1, 100609, December 2017

or I have offered the patient information about the procedure but this has been declined.

3. This procedure will involve:
   - General and/or regional anaesthesia
   - Local anaesthesia
   - Sedation
   - None

Signed (Health professional): ___________________________ Date: __________/________/______

Name (PRINT): ___________________________ Time (24hr): _________:___

Designation: ___________________________ Contact/bleep no: ___________________________

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1. Creutzfeldt Jakob disease (CJD)
   Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional.

   - Yes
   - No

2. Photography, Audio or Visual Recording
   a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment.

   - Yes
   - No

   b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.

   - Yes
   - No

3. Students in training
   I agree to the involvement of medical and other students as part of their formal training.

   - Yes
   - No
Consent Form

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4 Use of Tissue
a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research.

Yes  No

b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records.

Yes  No

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient):  Date: D.D./M.M./Y.Y.Y.Y.
Name of patient (PRINT):  

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.
Signed:  Date: D.D./M.M./Y.Y.Y.Y.
Relationship to patient:

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.
Signed (Witness):  Date: D.D./M.M./Y.Y.Y.Y.
Name of witness (PRINT):  
Address:

For staff use only:
Hospital number:
Surname:
First names:
Date of birth:
NHS no: _ _ _ / _ _ _ / _ _ _
Use hospital identification label

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Cyanoacrylate Glue Closure for Varicose Veins, V1, December 2017
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D Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): .................................................. Date: ...D.D./.M.M./.Y.Y.Y.Y...
Name (PRINT): ........................................................................ Job title: ..............................................................

Please initial to confirm all sections have been completed:

E Interpreter’s statement (if appropriate)

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

Signed (Interpreter): .......................................................... Date: ...D.D./.M.M./.Y.Y.Y.Y...
Name (PRINT): ........................................................................

Or, please note the language line reference ID number:

F Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): .......................................................... Date: ...D.D./.M.M./.Y.Y.Y.Y...
Signed (Health professional): ............................................. Date: ...D.D./.M.M./.Y.Y.Y.Y...
Name (PRINT): .......................................................... Job title: ..............................................................

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