

**Participant Information Sheet (Patient)**

**The AVERT** (Acute Vertebral Fracture Augmentation) Study

**Chief Investigator: Professor Opinder Sahota**

**PART 1**

**1. Invitation**

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully, and discuss it with others if you wish.

**PART 1 tells you the purpose of this study and what will happen to you if you take part.**

**PART 2 gives you more detailed information about the conduct of the study.**

Ask us if there is anything that is not clear, or if you would like more information. Take your time to decide whether or not you wish to take participate.

**2. What is the purpose of the study?**

Osteoporosis is a condition that makes bones more fragile and therefore more likely to break (fracture). Fractures of the spine are particularly common. The purpose of this study is to improve the treatment of fractures of the spine.

Vertebral augmentation is a general term for several techniques approved by the National Institute for Health and Care Excellence (NICE) used to treat painful spine fractures. Vertebroplasty is one such technique. This involves injecting bone cement into the fractured spine (vertebra) and is routinely performed for the treatment of these fractures and shown to improve pain.

However recent studies have shown that a nerve root block into the fractured vertebrae (similar to an injection when you attend the dentist), may be as effective as vertebroplasty in helping to relieve the pain. The nerve root block is a treatment approved by NICE for the treatment of acute sciatica (back pain which radiates down the leg). The advantage of this is that as well as helping to relieve the pain, you do not require an anaesthetic, which you do for a vertebroplasty.

Our study plans to compare a spinal nerve root block to vertebroplasty for the treatment of painful spine fractures.

The aim of both treatments is to improve pain control from your fractured spine and to allow you to mobilise as early as possible.

**3. Why have I been chosen?**

You have been invited to participate as you have been diagnosed with a painful spinal fracture.

**4. Do I have to take part?**

No, it is up to you to decide whether or not to take part.

If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are still free to leave (withdraw) from the study at any time without giving a reason. If you do decide to withdraw from the study, the study team would keep your records and data relating to the treatment given to you and the study measures up to the time that you withdraw, as this is valuable to the study. Your decision to withdraw at any time, or not to take part, will not affect the quality of care you receive.

**5. What will happen to me if I take part?**

The research team will be informed of your suitability by the doctors or nurses looking after you. With your permission, a researcher will explain the study to you in more detail and if appropriate, a member of your family. You will have at least 24 hours to consider the information and decide if you would like to take part.

If you agree to take part, a member of the research team will ask you to sign a consent form. Then the researcher will obtain information about you, your fractured bones and your hospital admission. The information about you will include an assessment of your general health, memory, pain, ability to walk, ability to perform personal care and use of pain medication. Once this information has been collected, you will then be allocated by chance, either to Vertebroplasty which is the usual treatment for this type of fractures or a spinal nerve root block,Medial Branch Nerve Block (MBNB).

The chance of being allocated to either group is 50:50. The team of doctors and nurses overseeing your care in hospital will be informed of which group you have been allocated to.

Both treatments will be assessed by a member of the surgical team performing the operation, an anaesthetist and by any other relevant medical profession identified by the doctors overseeing your care in hospital. They will discuss the allocated procedure, covering information on the procedure, risks and expected recovery time. The timing of the surgery will be determined by the hospital’s operating theatre capacity, but is expected to be undertaken within 48-72 hours after allocation. After surgery, you will be encouraged to get out of bed, led by members of the therapy team on the ward.

Whichever group you are allocated to, you will have access to regular pain medicine, assessment of nutrition, prevention of pressure sores, prevention of blood clots, regular input from members of the therapy team and assessment of your bone health.

A member of the research team will make contact with you after you have been recruited into the study to see how you are doing. There will be a:

A face-to-face meeting a week after joining the study

A telephone follow-up four weeks after joining the study

A telephone follow-up eight weeks after joining the study

As part of this study, you may also be invited to take part in a further interview conducted by the research team. If you agree to this you will be asked to sign an Interview Consent form. The purpose of this interview is to gain your insights into your condition, this study and its processes. This will lead to recommendations for how we can improve this study to help us build a larger future study.

The interview should last around 30 minutes and what is said will be completely confidential and when analysed, will be anonymised, which means nobody will know who gave the interview. A follow on, shorter interview will be done four weeks after you joined the study as part of the 4 week telephone interview. The interviews will be captured on a voice recorder by the research team using an audio/digital recording. All audio/digital recordings will be kept confidential, stored securely and deleted at the end of the study. During the study this recording will be sent securely, with your personal identifiable information removed (anonymised), to Clayton Research Support, an authorised professional transcription company, who will produce a written version of the interview for the research team to analyse. Arrangements for confidential handling, processing and destruction of data will then be made in accordance with the Data Protection Act 2018.

**6. What do I have to do?**

If you agree to participate in the study, a member of the research team will obtain the necessary information from you before you are allocated into one of the two groups. You will be asked about your symptoms and your general health and asked to complete a series of questionnaires at the start (baseline).

The next time you will be contacted by a member of the research team will be at your follow up visits.

**7. What is the procedure that is being tested?**

We are evaluating whether a nerve block in the spine is as effective as vertebroplasty and whether this procedure should become routine care for this type of injury.

**8. What are the alternatives for treatment?**

Alternative to surgery is to continue with pain medication and physiotherapy. Pain medication will be increased as necessary with regular assessment by the doctors and nurses overseeing your care.

**9. What are the side effects of any treatment received when taking part?**

If you do decide to take part in the study, you must report any problems you have to your nurse, doctor or member of the research team. There is also a contact number given at the end of this information sheet for you to phone if you become worried at any time. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

Complication rates with vertebroplasty are very low. Reported complication includes infection around the surgical site, cement leaking and pressing on the nearby nerves which may lead to pins and needles in the legs. Extremely rare is cement leaking in the blood which can cause a blood clot. This will be discussed when a member of the surgical team discusses the procedure with you.

**10. What are other possible disadvantages and risks of taking part?**

If you are participating in this research you will be randomised to have either standard care, which is vertebroplasty surgery, or instead a nerve root block for your spinal injury. Fluoroscopy imaging is used to guide these procedures, involving a small amount of ionising radiation, but you would have been exposed to this even if you did not participate in the research. The fluoroscopy required for the research procedure is around two thirds less than that from the standard care vertebroplasty. Exposure to radiation brings a small risk of causing cancer years in the future, but the level of risk from this exposure is considered minor.

Radiation is around us all the time in small amounts, from rocks in the ground and cosmic rays coming through our atmosphere. For example, when we take an international flight we get a small extra dose of radiation from cosmic rays, equivalent to a few days of background radiation.

Typically the radiation dose from vertebroplasty would be the equivalent of around two years of background radiation. For the nerve root block you'd receive the equivalent of a few months background. This would increase your risk of developing a terminal cancer years from now by around 1 in 8000. For comparison, our existing risk of developing terminal cancer is 1 in 4.

As explained earlier, the study aims to explore the use of an approved treatment by NICE in the form of a nerve root block, but for a different indication (fractured spine) to improve pain control. It is possible that if you were allocated to have the nerve root block injection, that this may not improve the pain from the fractured spine. If this is the case, you may need to be assessed for further treatment whilst you are in hospital.

The other disadvantage of taking part in the study is the inconvenience of the telephone call and a member of the research team visiting.

**11. What are the possible benefits of taking part?**

If you do take part in the study, you will receive treatment for the fracture of your spine, which would either be via Vertebroplasty (VP), which is considered to be standard of care or via Medial Branch Nerve Block (MBNB), which we anticipate to be as effective as vertebroplasty and is less invasive

**12. What happens when the research study stops?**

There will be no further contact from the research team when the study stops. The findings from the study will be assessed and we will look to seek further funding to develop a much bigger trial, which will look at the longer terms effects of the surgery and cost savings to the NHS.

**13. What if there is a problem?**

If you have concerns about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your question. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact PALS (Patient Advice and Liaison Service) telephone 0800 183 0204.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone’s negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**14. Will my taking part in this study be kept confidential?**

Yes. All the information about your participation in this study will be kept confidential. Details are included in Part 2.

**15. Contact Details**

**TEL EXT: 0115 924 9924 ext: 62067 (HCOP RESEARCH OFFICE)**

**EMAIL:** **maribel.cameron@nuh.nhs.uk**

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

**PART 2**

**16. What if new information becomes available?**

Sometimes during the course of a clinical trial, new information becomes available on the study being conducted. If this happens, we will tell you about it and discuss with you whether you want to or should continue in the study. If you decide to withdraw, we will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue. If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.

**17. What will happen if I don’t want to carry on with the study?**

You are free to withdraw from the study at any time. The research team will ask you for your reason for leaving, but you are not obliged to give reasons; they will also ask you to state the level of withdrawal, this will either be ‘Level 1 - complete’ or ‘Level 2 - with routine safety follow-up’. Level 2 withdrawals would allow the research team to have access to any of your data collected as part of routine care up to 12 months for long term safety analysis, which would be valuable to the completion of this feasibility study. For either level of withdrawal you would receive no further contact from the study team and would attend no further visits or measures; this information will be recorded in your medical notes and in the study documents. Withdrawing from the study will not affect the care you will receive. Any data collected up to the point of withdrawal will be kept and will be used in the final analysis. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

**18. Will my part in this study be kept confidential?**

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper and electronically at the Queens Medical Centre, under the provisions of the General Data Protection Regulation and other relevant UK legislation. Your name will not be passed to anyone else outside the research team, the sponsor, who is not involved in the trial. You will be allocated a trial ID number, which will be used as a code to identify you on all trial forms.

All information collected about you for the study will be kept strictly confidential and stored securely in accordance with ethical and regulatory requirements. Data stored will be made non-identifiable and anonymised using a unique Participant ID number. Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

Your records will be available to people authorised to work on the trial but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

**19. Use of Your Personal Data in Research**

All the information about your participation in this study will be kept confidential. We will keep all information about you safe and secure.

If you consent to take part in this study, the records obtained while you are in this study as well as related health records will remain strictly confidential at all times. The information will be held securely on paper, and electronically at your treating hospital under the provisions of the General Data Protection Regulation and the Data Protection Act. Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. You will be allocated a trial number, which will be used as a code to identify you on all trial forms.

If you withdraw consent from further study treatment, your data and samples will remain on file and will be included in the final study analysis.

In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made. The information collected about you may also be shown to authorised people from the Health Research Authority and the independent Ethics Committee to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.We will need to use information from you & your medical records for this research project. This information will include your:

* Initials
* NHS number
* Name
* contact details
* relevant past medical history
* medication history

held by site and / or sponsor for the research.  People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

You can find out more about how we use your information:

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* our GDPR leaflet available on request from researchsponsor@nuh.nhs.uk; or by the following link [www.nuh.nhs.uk/gdpr](http://www.nuh.nhs.uk/gdpr)
* by asking one of the research team
* by emailing the Data Protection Officer for NUH at dpo@nuh.nhs.uk,
* by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)

**20. Informing your General Practitioner (GP)**

Your GP will be informed of your participation in this study. By signing the consent form you will be agreeing that your GP can be notified.

**21. What will happen to any samples I give?**

There will be no samples obtained as part of this study.

**22. Will any Genetic testing be done?**

No genetic testing will be done.

**23. What will happen to the results of this clinical trial?**

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication. Should you wish to see the results, or the publication, please ask the research team.

**24. Who is organising and funding this clinical trial?**

The Nottingham University Hospitals NHS Trust will act as sponsor for the research. The National Institute for Health Research, Research for Patient Benefit research programme will fund the research.

**25. Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS by an independent Research Ethics Committee.

The study has also been reviewed and approved by the Health Research Authority and the Research & Innovation department of Nottingham University Hospitals NHS Trust. The Nottingham University Hospitals NHS Trust will act as the ‘Sponsor’ (i.e., the lead NHS hospital) for this research. The National Institute of Health Research (NIHR), Research for Patient Benefit (RfPB) will fund this research.

**26. Contact for further information**

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to the research team, who will be able to provide you with up to date information about study. If you wish to read the research on which this study is based, please ask the research team. If you decide you would like to take part then please read and sign the consent form. You will be given a copy of this information sheet and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor. You can have more time to think this over if you are at all unsure.

**TEL EXT: 0115 924 9924 ext: 62067 (HCOP RESEARCH OFFICE)**

**EMAIL:** **maribel.cameron@nuh.nhs.uk**

**Thank you for taking the time to read this information sheet and to consider this study.**