**Personal Consultee Information Sheet**

**The AVERT** (Acute VertEbRal augmentaTion) Study

**Chief Investigator: Professor Opinder Sahota**

**PART 1**

1. **Invitation**

We feel that your relative/friend is unable to decide for himself/herself on whether to participate in this study. To help decide, we would like to consult you on whether or not they would want to be involved. We would ask you to consider what you know of their wishes and feelings. Please let us know of any advanced decision they may have made about participating in research or the proposed treatment.

To help with making this decision, it is useful 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 other family members if you wish.

**PART 1 tells you the purpose of this study and what will happen to your relative/friend if he/she takes 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 consider your relative/friend’s view on participating.

1. **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 of 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 their fractured spine and to allow your patient to mobilise as early as possible.

**3. Why has my relative/friend been chosen?**

Your relative/friend has been invited to participate as he/she has been diagnosed with a painful spinal fracture.

**4. Does my relative/friend have to take part?**

No. We are seeking your advice regarding your relative/friend’s wishes about participating in this study. If you decide that your relative/friend would have no objection in taking part, we will ask you to read and sign a declaration form and we will then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn (leave) from the study.

A decision to withdraw at any time, or a decision not to take part, will not affect the care your relative/friend will receive.

Your relative/friend can withdraw from the study at any time without giving a reason. This will not affect the care they will receive. We will use the information obtained up until that point for data analysis.

**5. What will happen to my relative/friend if they take part?**

A member of the research team will be informed of your relative/friend’s suitability by the doctors or nurses looking after him/her. A researcher will explain the study to you and gather as much information as possible to understand the views of your relative/friend. There will be at least 24 hours to consider the information and participation in the study.

If your relative/friend participates in the study, a member of the research team will ask you to sign a declaration form. The researcher will obtain information about your relative/friend, their fractured bones and hospital admission. The information will include an assessment of your relative/friend’s general health, memory, pain, ability to walk, ability to perform personal care and use of pain medication. Once this information has been collected, your relative/friend will then be allocated by chance (randomly) to

either the group that will proceed to have Vertebroplasty which is usual treatment for this type of fracture or the spinal nerve root block. The chance of being allocated to either group is 50:50. The team of doctors and nurses overseeing your relative/friend’s care in hospital will be informed of which group your relative/friend has been allocated to.

Both treatments will either be assessed by a member of the surgical team performing the operation, an anaesthetist or by any other relevant medical profession identified by the doctors overseeing their 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, he/she will be encouraged to get out of bed, led by members of the therapy team on the ward.

Whichever group he/she is allocated to, he/she will have access to regular pain medicine, assessment of bone health and nutrition, prevention of pressure sores and blood clots as well as regular input from members of the therapy team.

A member of the research team will then make contact with your relative/friend after they have been recruited into the study to see how he/she is 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, your friend/relative 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 Declaration form. The purpose of this interview is to gain insights into your relative/friend’s condition, this study and its processes. This will lead to recommendations for how we can improve this study to help us design 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 joining 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 does your involvement entail?**

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

**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 your relative/friend will continue with pain medication and physiotherapy. Pain medication will be increased as necessary with regular assessment by the doctors and nurses overseeing their care.

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

If your relative/friend participates in the study, any problems related to the study will be reported to the research team by your relative/friend’s nurse or doctor. 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 you or another relative or friend.

Complication rates with vertebroplasty are very low and will be discussed by the surgeon performing the surgery. Rare complications include infection around the surgical site, cement leaking out of the surgical site and pressing on the nearby nerves which may lead to pins and needles in the legs. An extremely rare complication is cement leaking into the blood which can cause a blood clot. Rare side effects of the spinal nerve root block include infection and pins and transient pins and needles feeling down the legs. Again further details will be discussed by the doctor performing the procedure.

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

If your relative/friend participates in this study, they will have x-rays performed as a routine part of the surgery. This will be used to guide the surgery, involving a small amount of x-ray (radiation). He/she may have follow-up x-rays as well. 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 participating in this research would be the equivalent of around two to three years of background radiation. This would increase their risk of developing a terminal cancer years from now by around 1 in 8000. For comparison, the existing risk of developing terminal cancer is 1 in 4.

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

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 your relative/friend was allocated to have the nerve root block injection, that this may not improve the pain from the fractured spine. If this is the case, your patient may need to be assessed for further treatment whilst you are in hospital.

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

If your relative/friend participates in the study, he/she will receive treatment for the fracture of his/her spine, which would either be via Vertebroplasty, which is considered to be standard of care or a spinal nerve root block, which is we anticipate to be as effective as vertebroplasty and 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 larger 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, do 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 your relative/friend is harmed during the research study there are no special compensation arrangements. If they are harmed and this is due to someone’s negligence then there may have grounds for a legal action for compensation but your relative/friend may have to pay their legal costs. The normal National Health Service complaints mechanisms will still be available to them.

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

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

**15. Contact Details**

**TEL EXT: 0115 924 9924 ext: 82100 (HCOP RESEARCH OFFICE)**

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

This completes Part 1 of the Information Sheet.

If based on the information in Part 1 you do not see your relative or friend objecting to participating in this study, please continue to read the additional information in Part 2.

**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 and your relative/friend about it and discuss whether your relative/friend would like to continue in the study. If you would like for your relative/friend to be withdrawn from the study, we will make arrangements for your relative/friend’s care to continue with the clinician in charge of their care. If it is agreed for your relative/friend to continue in the study, you will be asked to sign an updated declaration form.

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

**17. What will happen if my relative/friend doesn’t want to carry on with the study?**

Your relative/friend is free to withdraw from the study at any time. The research team will ask for reasons for leaving, but you and your relative/friend are not obliged to give any reason. They will also ask your friend/relative to state the level of withdrawal; this will either be ‘Level 1 - complete’ or ‘Level 2 - with routine safety follow-up’. Level 2 withdrawal would allow the research team to have access to any of your friend/relatives 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 your friend/relative would receive no further contact from the study team and would attend no further visits or measures; this information will be recorded in their medical notes and in the study documents. Withdrawing from the study will not affect the care your relative/friend 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 relative/friend’s data will be securely stored for a minimum of 5 years. Arrangements for confidential destruction will then be made.

**18. Will my relative/friend’s part in this study be kept confidential?**

If your relative/friend takes part in this study, the records obtained while they 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 relative/friend’s name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. They will be allocated a trial ID number, which will be used as a code to identify them on all trial forms.

All information collected about your relative/friend 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.

Your relative/friend’s records will be available to people authorised to work on the trial but may also need to be made available to the people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your declaration form may be sent to the Research Sponsor during the course of the study. By signing the declaration form you agree to this access for the current study and any further research that may be conducted in relation to it, even if your relative/friend withdraws from the current study.

Unless informed otherwise, your relative/friend’s GP, and other doctors who may be treating them, will be notified that they are taking part in this study.

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

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

If you have advised to us that you have agreed for your relative/friend to take part in this study, the records obtained while they 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 their treating hospital under the provisions of the General Data Protection Regulation and the Data Protection Act. Their name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the trial. They will be allocated a trial number, which will be used as a code to identify them on all trial forms.

If you choose to withdraw them from further study treatment, their data collected to date 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, their data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made. The information collected about them 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 them as a research participant. We will need to use information from their medical records for this research project. This information will include their:

* 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 their records to make sure that the research is being done properly. People who do not need to know who they are will not be able to see their name or contact details. Their data will have a code number instead.

You can find out more about how we use your relative/friend’s 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 relative/friend’s General Practitioner (GP)**

Your relative’s/ friend’s GP will be informed of their participation in this study. By signing the declaration form you will be agreeing that they can be notified.

**21. What will happen to any samples my relative/friend gives?**

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 or your relative/friend 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, Department of Health will fund the research.

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

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) programme will fund this research.

**26. Contact for further information**

If you or your relative/friend has any questions about the study, please speak to the research team, who will be able to provide you with up to date information about the study. If you or your relative/friend wishes to read the research on which this study is based, please ask the research team.

If you decide your relative/friend would not have objected to participating in this study, then please read and sign the declaration form. You will be given a copy of this information sheet and the declaration form to keep. A copy of the form will be filed in your relative/friend’s 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: 0115 924 9924 ext: 82100 (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**.