Bone & Joint Open

Supplementary Material

10.1302/2633-1462.61.BJO-2024-0076.R1

CONSENT FORM

Title of Trial: ***Is the Rate of Early mobilisation in Hip fracture patients using Alfentanil Better than standard opioid analgesia (REHAB): A PROSPECTIVE COHORT STUDY***

Participant Identification Number for this trial:_____

Please **initial** each box to confirm that you have read and agree with each of the statements below.

1. I confirm that I have read the information sheet dated 21/10/23 (version.3.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I give permission for the research team to access my medical records for the purposes of this research study ☐

4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records ☐

5. I give permission for my personal information (including name, age, gender, weight, height, co-morbidities, location and functional status prior to admission, cognition, telephone number, and consent form) to be collected and retained on NHS Lothian servers for administration of the study. ☐

6. I give permission for my Community Health Index (CHI) number or hospital number to be collected and retained on NHS Lothian servers. ☐

7. I understand that data collected about me during the study may be converted to anonymised data. ☐

8. I agree to potentially being re-contacted by telephone, both 1 week and/or 1 month after the hip fracture surgery to assess the mid to longer term outcome of my hip fracture surgery. ☐

9. I agree to take part in the above study. ☐

Name of Person Giving Consent	Date	Signature
Name of Person Taking Consent	Date	Signature

PHYSIOTHERAPY ASSESSMENT FORM

Title of Trial: *Is the Rate of Early mobilisation in Hip fracture patients using Alfentanil Better than standard opioid analgesia (REHAB): A PROSPECTIVE COHORT STUDY*

POST OPERATIVE DAY 1

Time pain was assessed: _____

Time physiotherapy was conducted: _____

Analgesia given: _____

Was the patient assessed within 30 minutes of analgesia provision: (please circle one) YES NO

If above was answered "NO" please state the time pain was reassessed, if further analgesia was given and when physiotherapy was conducted.

Time pain was assessed: _____

Time physiotherapy was conducted: _____

Analgesia given: _____

PAIN ASSESSMENT

- Premobilisation pain at rest (on a scale of 0/10) ☐
- Premobilisation pain after passive hip flexion assessment (on a scale of 0/10) ☐

☐

- Post mobilisation pain (on a scale of 0/10)

FUNCTIONAL STATUS ACHIEVED

- PT level 1 -> standing transfer *(Please fill box either ✓or ✗)* ☐
- PT level 2 -> stepping transfer *(Please fill box either ✓or ✗)* ☐
- PT level 3A -> mobilising to the toilet with assistance of two peop
  (Please fill box either ✓or ✗) ☐
- PT level 3B -> mobilising to the toilet with assistance of one pers
  (Please fill box either ✓or ✗) ☐
- PT level 3C -> mobilising to the toilet without assistance
  (Please fill box either ✓or ✗) ☐

POST OPERATIVE DAY 2

Time pain was assessed: _____

Time physiotherapy was conducted: _____

Analgesia given: _____

Was the patient assessed within 30 minutes of analgesia provision: (please circle one) YES NO

If above was answered “NO” please state the time pain was reassessed, if further analgesia was given and when physiotherapy was conducted.

Time pain was assessed: _____

Time physiotherapy was conducted: _____

Analgesia given: _____

PAIN ASSESSMENT

- Premobilisation pain at rest (on a scale of 0/10) ☐
- Premobilisation pain after passive hip flexion assessment (on a scale of 0/10) ☐
- Post mobilisation pain (on a scale of 0/10) ☐

FUNCTIONAL STATUS ACHIEVED

- PT level 1 -> standing transfer *(Please fill box either ✓or ✗)* ☐

- PT level 2 -> stepping transfer *(Please fill box either ✓or ✗)* ☐

- PT level 3A -> mobilising to the toilet with assistance of two peop ☐
  (Please fill box either ✓or ✗)

- PT level 3B -> mobilising to the toilet with assistance of one pers ☐
  (Please fill box either ✓or ✗)

- PT level 3C -> mobilising to the toilet without assistance ☐
  (Please fill box either ✓or ✗)

IS THE RATE OF EARLY MOBILISATION IN HIP FRACTURE PATIENTS USING ALFENTANIL BETTER THAN STANDARD OPIOID ANALGESIA (REHAB):

A PROSPECTIVE COHORT STUDY

WE INVITE YOU TO TAKE PART IN OUR RESEARCH STUDY

- This information leaflet has been given to you because you have been admitted to the Royal Infirmary of Edinburgh with a hip fracture. Thank you for reading this leaflet for the REHAB Study. We invite you to take part.
- To help you decide whether or not to take part, it is important that you understand why the research is being done, and what it will involve. Please take the time to read this information carefully. Take time to decide whether or not you wish to take part. Feel free to discuss this with others, to aid your decision.
- Please contact us if there is anything that is not clear, or if you would like more information.
- The research team may contact you regarding this study and your potential inclusion.

Please note: You are free to decide whether or not to take part in the study. Please be assured that your decision with regards to involvement within the study will **NOT** affect the quality of care that you will continue to receive from your surgeon.

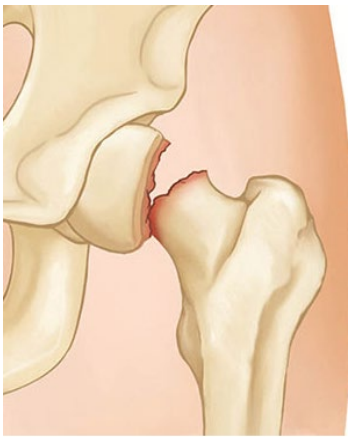
ABOUT THE REHAB STUDY

- We advise an operation to fix the hip, to help improve pain and allow you to walk again. After the operation, the team will encourage you to put weight on the injured leg and walk as soon as possible to help accelerate your recovery.

- In order to manage your pain, and facilitate early movement, you may be given painkillers (either **Oxycodone** or **Alfentanil**).
- Our study aims to assess how effective the two painkillers are, in order to determine the best pain management option after hip fracture surgery.

WHY ARE WE DOING THIS RESEARCH STUDY?

- **Getting up and moving early** after hip fracture surgery is associated with **lower rates of complications** which include infection at the operation site, chest infections, blood clots and death. As such, we try to encourage all our patients who have had an operation for hip fractures, to move as soon as they can.



- One of the main barriers to getting up after surgery is pain. We provide specific painkillers (on top of the normal ones you would receive after surgery) to help reduce pain before you try to get up and move. Currently, oxycodone is our painkiller of choice.

- Some work conducted by the department suggests a different painkiller called alfentanil may be more effective. **We are conducting this study, to see if alfentanil is better than oxycodone in improving pain after your surgery, to help you get up and move quicker!**

WHAT ARE WE DOING?

- We are carrying out a research study to see if we can manage your pain better before you move, with either alfentanil or oxycodone.

- We are recruiting 64 patients to participate in this study.

- Patients will be followed up based on the painkiller they receive. This is **up to the discretion of the medical team in charge of your care.**

- We aim to have 32 patients in each group: 32 patients receiving oral oxycodone and 32 patients receiving sublingual (medicine under the tongue) or subcutaneous

(injection of medicine under the skin) alfentanil. We will then compare the outcomes of the two groups.

WHAT WOULD TAKING PART INVOLVE?

BEFORE THE OPERATION

- If you decide to take part in this research study, you will be asked to sign a consent form. We will then complete a basic questionnaire with you regarding your height, weight, age, gender, cognitive status, location and functional status prior to admission and health conditions.

- You will receive the same standard of care as patients who are not involved in this study.

AFTER THE OPERATION

- Taking part in the study **will not affect your waiting time for surgery**. You will be admitted and **receive the same standard of care** during your hospital stay.

- After the operation, you will be taken back to one of the orthopaedic surgical wards. The team will optimize your pain, and help you gain the confidence and strength to walk again.

- You will work with physiotherapists, experts in exercise, to help you walk. They will assess your pain beforehand. If they feel you would benefit from additional painkillers, this will be given to you. This could be either oxycodone or alfentanil. This is up to the discretion of the medical team in charge of your care.

- If you are not in pain, additional painkillers may not be provided.

- We will **conduct questionnaires** with you at various points during your hospital stay to **determine how your pain and discomfort levels are**. This will help us see if getting you up and moving early has a positive effect.

FOLLOW UP VISITS

- You will be followed up by a member of the research team, at **1 day, 2 days, 7 days and 30 days after your operation.**

- A questionnaire (similar to the one described above) will be filled out with you to see how you are doing one week and one month after your surgery. **You may have been discharged at this point, and we will contact you via phone call to complete this**.

BENEFITS OF TAKING PART

- The benefit of taking part in this study is that you may be able to better work with physiotherapists to get up and move earlier. Getting up earlier after surgery improves your outcomes and reduces the risks of complications.

- The results of this study will be of **benefit to the future care of patients undergoing hip fracture surgery** and will help us become more aware of how to better control pain post-surgery.

POTENTIAL DISADVANTAGES OF TAKING PART

- The risks for the two groups are the same as those for any hip fracture surgery which include infection, stiffness, instability, pain, scar sensitivity and potential requirement for revision surgery.

IS THERE ANYTHING I NEED TO DO OR AVOID?

- No there is nothing you need to do! Each step of your journey will be discussed with you by the ward team. Your orthopaedic surgeon will discuss at length the most suitable treatment for you, and if applicable when surgery in hospital would take place.

- When you undergo surgery, you will be given instructions on when to fast prior to the operation. After your surgery, you will be brought back to the orthopaedic wards, where you will be taken care of by the ward team.

- You will be provided with all the pain medication you regularly take prior to admission (if applicable). You will also be given additional painkillers to help with post-operative pain. You will be prescribed oral oxycodone or subcutaneous (injection of medicine under the skin) alfentanil, purely for prior to physiotherapy. Decisions on further painkillers will be made by the ward team, and if appropriate, discussion with the specialist pain team at the hospital.

- We would advise that since you may be given opioid medications, that you do not take benzodiazepine medications (such as midazolam). You should also avoid alcohol. This will be further discussed with you by the ward pharmacist and medical team.

WHAT IF THERE ARE ANY PROBLEMS?

- If you have a **concern about any aspect of this study**, please contact Mr Nick Clement:
    - Phone: 0131 2426462 or
    - Email: Nick.Clement@nhslothian.scot.nhs.uk

- In the **unlikely event that something goes wrong,** and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lothian but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

WILL TAKING PART IN THE RESEARCH BE CONFIDENTIAL?

- NHS Lothian is the sponsor for this study based in the United Kingdom. **All the information we collect during the course of the research will be kept confidential** and there are strict laws which safeguard your privacy at every stage.

- Your rights to access, change or move your information will be limited, as we need to manage your information in specific ways for the research to be reliable and accurate**. If you choose to withdraw from the study, we will keep the information that we have already obtained about you.**

- **To safeguard your rights, we will use the least possible personally-identifiable information.**

- For **further information** about the use of personal information and data protection, please visit:
    - www.nhsinform.scot/care-support-and-rights/health-rights. - Use of personal information
    - www.nhslothian.scot.nhs.uk/YourRights - NHS Lothian Data protection

WHAT IF I DON'T WANT TO CARRY ON WITH THE STUDY?

- **You are free to decide at any time during the study to withdraw consent and stop participating**.

- Please be assured that **your decision with regards to involvement within this study will not affect the quality of care** that you will continue to receive from your surgeon. Withdrawal from the study **does not pose any safety issues to you.**

- Should you decide to stop further involvement in this study, **we will retain all data we have collected up to that point.** All physical copies of your information will be destroyed. All electronic data we keep, will be anonymized, such that no personal data will be retained. We will then exclude you from all planned research study follow ups.

- Should you wish to withdraw from the study, **please inform your medical team.**

WHAT HAPPENS WHEN THE STUDY IS FINISHED?

- Once the study ends (which will occur after the 1 month follow up for the final patient included in this study), **all physical copies of personal data will be kept for 1 year.** This will be stored in a confidential locked cabinet in a locked room in the Royal Infirmary of Edinburgh, Trauma & Orthopaedic Surgery department. After this time, all personal data will be destroyed using confidential waste bins.

- All electronic data collected during the study, **will be stored in a database on secure NHS Lothian servers**. This database will be created in a password protected excel file held on an NHS Lothian hard drive (S-drive), with access limited to the research team only. All personal data will be removed from the information included in this database. **This data will be kept for 5 years.** After this time, the data will be overwritten with a series of characters and deleted from NHS servers. No data will be sent to any third parties at any point during or after the study.
- After the end of the study, **the data collected will be analysed and a report will be compiled and published in a peer reviewed journal**. Should you wish to gain access to this report or an explanation of the findings from the data extracted, we are happy to provide this to you.

HOW WILL WE USE YOUR PERSONAL INFORMATION?

- We will need to use information from your medical records for this research project. We will collect your **Community Health Index (CHI) number**

Please note: The CHI is a population register, used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index and is personal identifiable information. Your CHI number is being collected to allow us to access your medical records for the purposes of determining if you meet the criteria for admission into this study. Furthermore, this allows us to follow your inpatient journey and be kept up to date with any issues with your treatment.

- Other personal identifiable information collected will include your **telephone number, name, age, gender, weight, height, co-morbidities, location prior to admission, functional status prior to admission and cognition**. Members of the research team 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 assigned instead. We will keep all information about you safe and secure in our research database, on secure NHS Lothian servers, as mentioned in the previous section.

- Individuals from NHS Lothian and regulatory organisations may look at your medical and research records to assess the accuracy of the research study.

- Only people in NHS Lothian who need to contact you for your research follow-up appointments, or audit the data collection process will have access to information that identifies you. The people who analyse the information will not be able to identify you and will not have access to your name, NHS CHI number or contact details. NHS Lothian will keep your personally identifiable information for 1 year after the study has finished.

- In all reports made public, analysis and data will be presented in a completely anonymized manner.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

- **You can choose to withdraw from the study at any time**, without giving a reason. However, we will keep information about you that we already have.

- We need to manage your records in specific ways for the research to be reliable. This means that **we won't be able to let you see or change the data we hold about you.**

FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to [Nick.Clement@nhslothian.scot.nhs.uk], or
- by ringing us on [0131 2426462].

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

- This study will be written up as a publication, to be submitted to a peer reviewed medical journal. It may also be presented at various surgical conferences. **You will not be identifiable from any published results.**

- If you would like access to the results of the study, please contact Mr Nick Clement at Nick.Clement@nhslothian.scot.nhs.uk. This will be then provided to you via email.

ORGANISATION AND DEVELOPMENT OF THE STUDY

- This study has been **organised by the Trauma & Orthopaedic Surgery team at the Royal Infirmary of Edinburgh**. It will be **sponsored by NHS Lothian**. There will be no funding for this study. The study proposal has been reviewed by all members of the research team and members of the Trauma & Orthopaedic Surgery department.

- **Patients have been involved in the development of this study**. Reasons were sought as to why patients were unable to move immediately after their hip fracture surgery. The most common answer was due to post operative pain. This has been kept in mind when designing this study.

- All research in the NHS is looked independently by a research ethics committee. **NHS Management Approval has also been given.**

WHERE WILL THIS INFORMATION BE STORED?

- All physical copies of personal data will be stored in a confidential locked cabinet in a locked room in the Royal Infirmary of Edinburgh, Trauma & Orthopaedic Surgery department. This will be kept for up to 1 year after the end of the study. After this time, all personal data destroyed using confidential waste bins.

- All electronic data collected during the study, will be stored in a database on secure NHS Lothian servers. This database will be created in a password protected excel file held on an NHS Lothian hard drive (S-drive), with access limited to the research team only. All personal data will be removed from the information included in this database. This data will be kept for 5 years. After this time, the data will be overwritten with a series of characters and deleted from NHS servers. No data will be sent to any third parties at any point during or after the study.

FURTHER INFORMATION AND QUESTIONS

If you have any **further questions about the study**, please contact **Mr Nick Clement** on:

- Phone: 0131 2426462 or
- Email: Nick.Clement@nhslothian.scot.nhs.uk

If you would like to **discuss this study with someone independent of the study team,** please contact **Mr Andrew Duckworth** Consultant Orthopaedic Surgeon on:

- Phone 0131 2421182 or
- Email: Andrew.Duckworth@nhslothian.scot.nhs.uk

If you wish to make a complaint about this study, please contact NHS Lothian:

Patient Experience Team
NHS Lothian
2nd Floor Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 536 3370

Email: feedback@nhslothian.scot.nhs.uk