Epidural Fentanyl in the treatment of Post-operative pain following lumbar laminectomy

Information for Patients

You are being invited to take part in a research study. Before you decide 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 relatives and friends if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Consumers for Ethics in Research (CERES) publish a leaflet entitled ‘Medical Research and You’. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London N16 0BW.

Thank you for reading this.

What is the purpose of the study?

You are waiting to have a back operation called a lumbar laminectomy. This operation involves cutting past some muscle and removing bone from the back. It is usual to give pain killers after the operation to control the discomfort. We are investigating whether we can improve the pain control by using a technique called an epidural.

“Epidurals” have been used very successfully to control the pain of childbirth and pain during or following operations. We want to investigate whether they can be used to control pain following spinal operations.

To perform an epidural at the end of the operation is quite straightforward. The surgeon inserts a tube along the membrane that runs around the spinal cord. A single dose of a pain killer called fentanyl can then be given and the tube is removed before your back is stitched up.

Why have I been chosen?

You have been chosen because you are waiting to have a lumbar laminectomy.
Do I have to take part?

No, you do not have to take part. If you decide not to participate it will not affect your care in any way.

What will happen to me if I take part?

If you agree to take part in this study you will be randomly allocated to either receive the pain killer fentanyl as an epidural or to the “control” group in which case you will be given the standard post-operative pain killers but will not receive an epidural. Random allocation means that neither you nor your doctor will be able to choose whether you have an epidural or not. It is also important for this study that you do not know whether you have had the epidural or not. (However, on completion of the study we will let you know).

What do I have to do?

After the operation you will be asked for a “pain score” to assess how severe the post-operative pain is. This will occur on the day of surgery, on the first and second post-operative day. There is also a short questionnaire to fill in prior to discharge. A nurse will also ask you to complete pain scores as part of your normal routine post-operative care.

We will collect details of the additional pain killers you may have required, and the length of time you spend in hospital. We will also need your name and address so that on completion of the whole study we can let you know what we have found.

What is the procedure being tested?

This is not a new procedure – fentanyl is routinely used in epidurals. However most epidurals also have a local anaesthetic in them. Local anaesthetics can stop the nerves from working and we therefore avoid using them when doing operations on the spine.

What are the alternative treatments?

The alternatives to epidural fentanyl are pain killers taken as tablets, into veins or even as suppositories. Participating in this study does not stop you having some or all of these other medications. In fact one of the things we will measure is the amount of other medication you require.
What are the risks or benefits of taking part?

The main benefit of taking part is that the control of pain may well be better. Consequently, patients are likely to get out of bed and hospital sooner and this reduces the risks of blood clots in the legs and hospital infections.

Occasionally, fentanyl may cause temporary side effects such as feeling sick, vomiting, dizziness, sleeplessness and lack of sexual desire. Other effects which have been reported include a slight, temporary lowering of blood pressure or irregular heartbeat. It will also cause breathing rate to fall and may cause a lowering of your heart rate. These effects are normal when receiving this type of medicine. It has also been reported that a patient may stop breathing temporarily. The doctor has drugs to reverse this effect. All of these side effects are rare.

Epidural fentanyl is known to carry a slightly higher risk of temporary itching and bladder problems. Epidurals carry a very small risk of a spinal blood clot which could in the worst case scenario result in paralysis. The risk is estimated as 1 in 2,250,000 or 0.00005%.

What if new information becomes available during the study?

If any new information becomes available during the course of this study your consultant will inform you of this.

What if something goes wrong?

If you participate in this study your hospital consultant remains in charge of your medical care. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study the normal National Health Service complaints mechanism is available to you.

Will my taking part in this study be kept confidential?

All information collected about you or from you will be treated as strictly confidential. All the data is stored by the co-ordinating centre at Newcastle University. The staff at Newcastle will maintain the confidentiality of all the data they store. With your permission they will inform your GP that you are taking part in the study.

What will happen to the results of the study?

It is anticipated that the data from this study will be published in medical journals. When this happens it will be presented anonymously and it will not be possible to identify any individual. The study will be completed and reported in 2007.
Who has reviewed this study?
This study has been reviewed by the relevant NHS Research Ethics Committees.

Contact for further details.
If you have any questions about the study please speak to the Local Co-ordinator

Mr Patrick Mitchell
Tel: (0191) 256-3484

Please retain this sheet for your future information.