

# RESEARCH INFORMATION SHEET FOR PATIENT'S RELATIVES

## Decompressive craniectomy following traumatic brain injury

Following injury to the head the brain, just like any other part of the body, becomes bruised and swollen. This swelling occurs in the confines of the rigid skull and results in an increase in pressure and reduction in blood and oxygen supply to the brain.

Treatment of your relative on the intensive care unit is directed at controlling this swelling and pressure and maintaining a good blood and oxygen supply to the brain. There are a number of conventional treatments that we use to achieve this including the ventilator to support breathing and various drugs to support blood pressure and reduce swelling directly. Whilst these treatments are effective in some patients, others with more severe swelling are at an increased risk.

We are therefore looking at other ways to control brain swelling and reduce high pressure. These include the use of an operation called a decompressive craniectomy. The rationale is to remove part of the skull bone at the front of the head leaving the brain protected by the membranes and scalp. This creates an opening for the brain helping to control swelling and high pressure. We later repair the opening using the original bone or a synthetic plate. An alternative is to use medical treatment with stronger drugs to control the activity of the brain. The benefits from these treatments and which technique is effective for a particular type of patient is currently unclear. We would therefore like you to consider taking part in a study to help us direct the best treatment.

If your relative requires these more advanced measures to control pressure and swelling we are seeking your consent to randomize i.e. select by chance in the first instance either the operation to control the swelling or the medical treatment. If either treatment is not effective than we can use the other treatment as an alternative if necessary so your relative is not being deprived of a potentially beneficial therapy. Six months, one year and two years following the head injury we will contact you to complete a questionnaire to assess progress. We would also like to perform a further brain scan at six months after the injury.

While this study will help to control the brain swelling and pressure in your relative, it is important to emphasize that this is a research project and as such you may withdraw your relative from this study at any time without explaining why. Whilst withdrawal from the study whilst in intensive care following surgery will not be possible, you will still be able to withdraw from the 6 month questionnaire and scan. If you wish to do this we would still like to use the results but only with your permission.

If you consent to this study all records of participation will be kept strictly confidential. Information held by the NHS and records held by the National Statistics office may be used to keep in touch with your relative and/or determine health status in the future. This study is not only being carried out in this hospital but also in other intensive care units across Europe.

For further information please contact .....