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Participant Information Sheet (PIS) for participants **[PIS-A]**

**Perioperative Outcome Study in the Elderly (POSE): European, Large Scale, Multi-Centre, Prospective Observational Cohort Study**

We would like to involve you in a clinical study we are conducting. The study is entirely voluntary, and you are free to withdraw from the study at any time.

**Introduction**

Before you decide, it is important that you understand why the study is being done and what it involves. One of our team will go through the study with you and answer any questions you may have. Please feel free to talk to others and please ask us if there is anything that is unclear**.**

**Background**

In Europe, it is estimated that the elderly population (≥80 years) will increase from 5.3% of the total population in 2015 to 9% in 2040. Compared with younger patients needing surgery, the elderly are at greater risk of complications after elective and especially emergency procedures. The results of this study may support health care systems to adapt to the patients´ needs (i.e. the need for critical care units for the elderly, more advanced monitoring devices, geriatricians in the surgical departments, or geriatric anaesthesia fellowship programs). Furthermore, the results may support future health facilities and budget planning.

**Why have I been asked to take part in the trial?**

You have been chosen to participate because your age is equal to or greater than 80 years and you are undergoing surgical and non-surgical interventions (e.g. radiological procedures or endoscopy), either elective or emergency, with anaesthesia care.

**Do I have to take part?**

No. Once you have read this information sheet, if you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason, and this will not affect the care you receive*.*

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

You will receive exactly the same treatment as if you did not participate but we will collect routine clinical data about you, your procedure and your recovery. We will also perform two extra assessments: a cognitive test and a timed ‘up and go’ test. The cognitive test will involve remembering a sequence of words and assess your ability to draw a clock face. The timed ‘up and go’ test involves standing up from a seated position, walking forward for three meters, turning around, walking back to the seat and returning to a seated position.

We will also invite you to participate in short questionnaire 30 days after your procedure. This will be conducted in person if you are still in the hospital or via a 3-5-minute telephone interview.

In the unlikely event of your death – we will continue to collect relevant information from your medical records, if required.

**What information is collected?**

For all patients included, we will record a few details such as name, age, hospital number, NHS number and telephone contact number and details about your care during and after the procedure.

**How is this information used?**

The information collected about you will be stored on a secure database. We will only use identifiable information so we can follow-up your recovery and can contact you for the 30-day questionnaire. This will only be accessible to the study clinicians and nobody else. No identifying information such as names, addresses or NHS/hospital numbers will be shared with the central team. The statisticians analysing the data cannot identify them.

**How secure is this information?**

The information is held on a secure computer system in the NHS and further anonymised information in the study databank in Germany. The study has been approved under the Data Protection Act by the lead site, Aneurin Bevan University Health Board.

**What are the possible disadvantages and risks of taking part?**

There are no disadvantages and no risks.

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

Participation in the trial might benefit you during your hospital stay. The cognitive and motoric testing (MiniCog, Timed up and go) at baseline will enable us to identify patients at higher risk for postoperative cognitive impairment, or mobility problems after intervention and that the study team will directly inform your doctor, if we find a deviant test-result, which was not recognized/known before testing. This could improve your care after the intervention e.g. providing a non-pharmacological measures to prevent delirium or more tailored support with the mobilization after the procedure. Due to the lack of information regarding the outcomes of elderly patients undergoing surgical and non-surgical interventions, you will be contributing to the knowledge that may support health care systems to adapt to the patients´ needs, leading to the development of future health facilities and contribute to budget planning.

**What if something goes wrong?**

If you wish to ask further questions, or complain about any aspect of the trial, please contact any of the trial organisers, or the NHS complaints procedure. The telephone number is ***[Insert Local contact details]*.**

**Will my taking part in this trial be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. All information that is collected about you during the course of the trial will be kept strictly confidential. Procedures for handling, processing, storing and destroying data are compliant with the Data Protection Act 1998.

**What will happen to the results of the trial?**

The trial is estimated to take one year to undertake, and it is hoped to publish the results during 2019. If you would like a copy of the published results, please contact your local principle investigator ***[Insert Local contact details]*. You will also be able to look at these on the study’s website: http://www.pose-trial.org**

**Thank you for taking the time to read this information.**

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