SQUEEZE Appendix 1A - Patient Information Sheet v1.0

SQUEEZE: Postoperative Vasopressor Usage: prospective, international multicentre cohort study

STUDY INFORMATION SHEET FOR PATIENTS:

This is an information sheet about an observational research study being conducted at your hospital. We would ask you to carefully read the following information.

Background

Some patients have transient low blood pressure the day after surgery. If the blood pressure is too low, then the healthcare team may want to treat the low blood pressure. The commonest treatment is intravenous fluids but occasionally an infusion of medication is required – typically, the medication is a drug that increase blood pressure (vasopressor). The amount of patients having low blood pressure after surgery and the use of the drug that increases blood pressure has never been described and that is the focus of this study.

What will happen in the study?

You are having surgery and may receive the drug that increases blood pressure. The healthcare research team will collect the following information:

- General information about your health status from your medical records, in particular about your medication and previous medical history.
- Data about the progress though surgery and after your operation.

All data will be anonymised. No data will be linked back to you
All information will be entered into a secure on-line database for subsequent analysis

Participation in the study will not affect the medical care you are going to receive in any way. In particular there will not be any additional interventions or tests.

How will the results be used?

The analysis will be disseminated through publication in scientific journals and at medical conferences.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks.

What are the possible benefits of taking part?

The information we get from this study will improve our understanding of the occurrence of low blood pressure after surgery and this might lead to improvement of care in the future.

Privacy and use of clinical information

To carry out the study it will be necessary to consult your medical record and collect some of the information that appears in it. The study authorised study personnel to consult and process the information in the following manner:

- Study participants will be identified by a number (encoding). The key linking the study number to your personal identification will be kept confidential and will be stored at your hospital in a locked cabinet accessible to authorised personnel only.
- Anonymised information i.e. only identified by a number and without link to personal identification will be stored in a central computerised database protected through personalised and confidential username and password. No data concerning personal identification will be stored in the central computer database.
- For purposes of monitoring, audits or inspections, the European Society of Anaesthesiology, national coordinating investigators, members of the relevant ethical board or regulatory authorities will be allowed to access all study documents, including identifiable information. All handling of personal data will comply with the Good Clinical Practice Guidelines and strictly follow the legal and national requirements for data protection.

Can I opt out?

Although we do not ask for written consent, you are under no obligation to take part. Declining to be involved will not affect the care you receive. If you change your mind then you are free to withdraw at any point, without giving a reason, and this will not affect the care you receive. If you decide to withdraw from the study no further data will be collected, but data that has already been collected, and encoded (identified by a number) will remain anonymised and used in subsequent analyses. Please talk to your local investigator if you decide to opt out.

Finally, we would like to draw your attention to the fact that this informative document refers only to your participation in the SQUEEZE study.

Funding and organisation of the study

This study is funded by the European Society of Anaesthesiologists. Your local investigator is:

Hospital Investigator: _____ Telephone: _____

Research Nurse: _____ Telephone: _____

If you have any questions related to your rights as a study participant, you can contact the local Ethics Committee or R&D office at: _____ Telephone: _____

Thank you for taking time to read this information sheet.