Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for patients who are invited to participate in the research

Research title: Assessment of Ultrasonographic Carotid Artery Corrected Flow Time and Internal Jugular Vein Collapsibility Index in Prediction of Hypotension during Induction of General Anesthesia

Introduction and aim of the work:

Hypotension during induction of general anesthesia, or postinduction hypotension, is quite common in clinical practice. If hypotension is severe or prolonged, it may cause organ hypoperfusion and ischemia. It may also increase the incidence of postoperative adverse outcomes such as myocardial injury, ischemic stroke, acute kidney injury, and even increases 1-year mortality.

Doppler corrected flow time (FTc) refers to the left ventricular ejection time corrected by heart rate. It is known to be proportional to left ventricular preload and cardiac inotropy and inversely proportional to systemic vascular resistance.

The aim of this study is to investigate the reliability of preanesthetic ultrasound measurements of the carotid artery FTc and the internal jugular vein collapsibility index in predicting hypotension during the induction of general anesthesia.

Place of work:

Anesthesia, ICU and pain management department, Ain shams university hospital

Number and Selection of participants:

The estimated sample size will be 63 patients undergoing general anesthesia.

Assuming that the dropout is of 10%, a sample size **at least 70 patients undergoing general anesthesia** will be needed.

Study interventions:

Plan of the work:

After your consent achievement and fully explained about the steps of research, the subjects of both groups will be subjected to the following:

1. Clinical parameters:

Complete history taking and thorough clinical examination

The study will be done by competent investigations

Inclusion Criteria:

1- Patients of American Society of Anesthesiologists (ASA) physical status I to II of both genders.

2- Aged 18-65 years.

3- Elective surgeries under general anesthesia.

4- BMI less than 40.

Exclusion criteria:

Patients with

1- Renal diseases.

2- Hepatic diseases.

3- ASA scores of 3-4.

4- The presence of a left ventricular ejection fraction less than 50%.

5- Age under 18 years old.

6- Patient refusal.

7- Coronary heart disease.

8- Cardiac disease including cardiomyopathy and mild to severe valve disease.

9- Pulmonary hypertension.

10- Peripheral arterial disease.

11- Preoperative cervical vascular ultrasound abnormalities including plaque, stenosis and anatomical variation.

12- Any previous neck surgery or trauma.

Benefits expected from the study:

Benefits to the participants:

To investigate the reliability of preanesthetic ultrasound measurements of the carotid artery FTc and the internal jugular vein collapsibility index in predicting hypotension during the induction of general anesthesia.

Benefits to the community:

Post induction hypotension is closely related to postoperative complications. Patients are at high risk of hypotension due to preexisting hypovolemia and the vasodilatory effects of induction agents. Ultrasonographic measurement of the Carotid artery corrected flow time and internal jugular vein collapsibility index could predict post induction hypotension.

Conducting the consent:

The consent will be conducted to the patient by the investigator, Doctor Marina Adel George and consent will be taken privately in a private room in anesthesia department, Ain Shams University Hospital. Literate individuals will be left to read the consent followed by its explanation by the mentioned investigator, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

This research will not expose your patient to further risks or complications despite the standard risks of protocol of Ain Shams University hospitals.

Neck Ultrasonopgraphy: is a non-invasive, rapid method to assess the site and anatomy of carotid artery and internal jugular vein. These waves carry no recognized risks or side effects and are not known to cause or aggravate any medical condition.

Alternatives to participating:

In case of refusing to participate in this research, your patient will be followed up and will receive his treatment as planned.

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the research is completed, you will be informed regarding your patient `s research results and also further information regarding your patient `s health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at anytime. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient’s participation is voluntary and you have the right to withdraw your consent

or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

Contact Information:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the investigator, Marina Adel George at mobile number 01033601117. You can also call the assistant supervisor Dr.Ahmed Taha at mobile number 01092344887 or Dr. Aya Hisham at mobile number 01114555939 or Dr. Sherif Sultan at mobile number 01128448448. If you have any problems or concerns about the study, you can also call Dr. Amir Salah the main supervisor at mobile phone number: 01222197592.

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my patient`s medical care.

- Name of participant:
- Signature of participant:
- Identity number or finger print: …….
- Date:

I have accurately read or witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher: Marina Adel George.
- Signature of researcher:
- Date:

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is a committee whose task is to make sure that research participants are protected from harm.

If you wish to find more about Ethical Committee of Scientific research. Contact:

Name:

Address:

Telephone number:

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