PROTOCOL OF A THESIS FOR PARTIAL FULLFILMENT OF M.D. DEGREE IN ANESTHESIA

Title of the Protocol:

A Comparative Study between Thoracic Epidural Anesthesia in Non-Intubated Video-Assisted Thoracoscopes and the Conventional General Anesthesia with One Lung Ventilation

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Ain Shams University

Faculty of Medicine

Ethical Committee of Scientific research

Informed consent form for parents or guardians of patients who are invited to participate in the research

Research title: Evaluation of serum interleukin-18 as a prognostic marker in patients with HCV related hepatocellular carcinoma

Introduction and aim of the work:

Hepatocellular carcinoma (HCC) is the fifth most common cause of cancer deaths worldwide. The incidence is rising, and is expected to increase by another 81% by 2020 primarily due to HCV epidemic.

The aim of the present study is to identify the Correlation between serum IL-18 level & clinical, laboratory, & radiological features of patients with HCC. & the prognostic value of IL-18 in patients with HCC**.**

Place of work:

Tropical Medicine Department, Ain Shams University Hospital.

Number and Selection of participants:

- Will be 55 participants, 35 participants are patients with HCC and 20 participants are healthy (age & sex matched), as a control group.

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

2. Laboratory parameters:

1. CBC.
2. Liver function tests (including coagulation profile, liver enzymes, albumin, bilirubin).
3. Viral markers: (HCVAb- HBsAg).
4. Renal profile in the form of serum creatinine, Na^+ and K^+ level.
5. Serum IL-18 level.

3. Radiological parameters:

Radiological assessment including the following:

1. Abdominal ultrasonography: to assess the status of liver parenchyma, splenomegaly, & presence of ascites.

In addition patients of group I will be subjected to:

a. Laboratory assessment of serum AFP level.
b. Triphasic abdominal CT: to assess site, size, & number of focal lesions.
c. Liver biopsy to confirm diagnosis of HCC will be done if indicated.

Patients of group I will be followed up for 1 year at 3 months interval by:

1. Clinical:

- Deterioration of present manifestations of liver disease.

- Development of new manifestations of liver disease.

2. Laboratory:

a. Liver function tests: Including total and direct bilirubin, AST, ALT, alkaline phosphatase, GGT, albumin, globulin, prothrombin time.
b. Kidney function tests: including serum urea and creatinine.
c. Serum Na and K.
d. Complete blood count (CBC).
e. Erythrocyte sedimentation rate (ESR).
f. Serum IL-18 level: done by ELISA technique at the end of 1 year of the technique used.

3. Radiological:

- Abdominal triphasic CT. (to monitor response to intervention, & detect recurrence & vascular invasion).
- Doppler U/S: (to detect vascular invasion if CT is not conclusive).

Benefits expected from the study:

Benefits to the participants:

Decrease HCC related morbidity & mortality by undergoing radiofrequency ablation for their focal lesions.

Benefits to the community:

To find out if there is a Correlation between serum IL-18 level & clinical, laboratory, & radiological features of patients with HCC, & also the prognostic value of IL-18 in patients with HCC.

Conducting the consent:

The consent will be conducted to the legal guardian or the patient by the investigator, Doctor Mohamed Abdel Fattah Mohamed in the Tropical Medicine 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.

- ***The risk of blood sampling:*** The blood sample will be obtained by a trained, professional nurse using sterile, disposable equipment. The risks of bleeding, bruising, or infection are small, and similar to having blood drawn at your doctor's office. Some subjects report a feeling of faintness or brief dizziness upon blood sampling. However, the volume of blood (5 milliliters) is small, and will be replaced quickly by your body.
- ***As for liver biopsy*****:** it will be done as clinically indicated for the condition of the patient. It is performed by highly skilled and well trained interventional radiologist; in a well equipped place should any complications happen. Although this procedure is usually safe and performed without difficulty, like any procedure there are complications that may occur. These are unusual (incidence does not exceed 2%) but you should be aware of them. Bleeding can occur rarely; sometimes it can require transfusions, or surgery to correct. Leakage of bile into the abdomen, leakage of blood or air into the chest, medication reaction, shock, perforation of the intestine, or development of a communication between an artery and a vein in the liver can occur, but are unusual. These complications may require urgent surgical interference or ICU admission which will be provided as needed. Deaths have been reported but are extremely rare. A biopsy of the lesion is required for the

diagnostic confirmation of HCC. A recent study showed that 84% of nodules >2 cm in diameter met the typical criteria of HCC and did not require biopsy confirmation. Although no procedure is absolutely safe, liver biopsy can provide valuable information for the treatment of liver problems, especially HCC. Your decision whether or not to participate in this study will not affect your patient's medical care.

- ***Abdominal Ultrasonopgraphy:*** is a non-invasive, rapid bedside method to assess status of liver, spleen, presence of ascites. This device uses ultrasound waves. These waves carry no recognized risks or side effects and are not known to cause or aggravate any medical condition.
- ***Triphasic CT***: It carries the potential risk of radiation exposure. A contrast agent will be injected into your vein in order to give a clearer image of the HCC with the potential risks of: bruising or swelling at the injection site. Occasionally, minor allergic reactions occur in the form of itching, sneezing, hives, swelling of the eyes, wheezing or nausea. These symptoms may require treatment with medication we have at hand. Rarely, a more serious reaction will occur. A radiologist will evaluate the situation and determine if additional medical treatment is necessary. Even though it is rare, medical statistics indicated that a fatality might occur from the injection of contrast.
- ***As for Radiofrequency ablation:*** It will be conducted under ultrasonographic guidance with no risk of exposure to radiation, also there is no risk of contrast exposure, there might be pain after intervention or it might be complicated by infection of the dead tissue to avoid such complications there will be close follow up by specialized doctors for patients after intervention during a post-intervention 5 days in-patient care.

Reimbursements in cases of risks and complications:

Should your patient get physically injured as a result of research-related procedures, Doctor Mohamed Abdel Fattah Mohamed will provide first-aid medical treatment.

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 complete, 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, Mohamed Abdel Fattah Mohamed at phone number: 24198944, mobile number: 0111230798. You can also call the assistant supervisor Dr. Amal Tohamy at mobile number: 0123971152. If you have any problems or concerns about the study, you can also call Prof. Zakaria Yehia Mahran the main supervisor at mobile phone number: 0101000289 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 legal guardian:
- Or 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: Mohamed Abdel Fattah Mohamed.
- 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: