

**HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION
PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL**

Lia Alves Martins Mota Lustosa

Advisor: Prof. Dr. João Manoel Silva Júnior

São Paulo

06/29/2022

INFORMED CONSENT FORM

Project title: **“HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL**

Responsible researcher: Juliano Pinheiro de Almeida -Institution: Hospital e Maternidade Sepaco, Adress: Rua Vergueiro, nº4210, Vila Mariana – São Paulo. Telefone: (11) 21824604

Voluntary Name: _____

Age: _____ anos

You are invited to participate in the research project: **“HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL ”**.

This form will provide you with all the information you need to know about this study. A member of the research team will describe this study to you and answer all your questions. Please, before deciding to participate in the study, carefully read the detailed information and clarify any doubts that you consider necessary before making the final decision.

For some people who may have some type of disability that makes it impossible to make decisions for themselves, the legal guardian will be asked to decide to participate in the study, please read this informed consent form carefully.

WHY IS THIS CLINICAL STUDY CARRIED OUT?

Dear Mr/Ms, you will undergo arthroscopy shoulder surgery.

There are two anesthetic techniques described in the literature for performing this procedure: general anesthesia + interscalene block and sedation + interscalene block.

Both techniques can normally be used to perform this type of surgery, in current practice.

However, there are few studies stating that the sedation + block technique can generate fewer side effects, such as lower blood pressure reduction and fewer complications resulting from the decrease in blood pressure. Since any anesthetic technique promotes changes in the heart, such as a decrease in blood pressure.

This option may offer greater care during the surgical procedure.

Below you will find information about this study, its role, risks, restrictions and benefits of your participation and the informed consent form.

You are free to accept or reject your participation in this registry; this does not change the quality of the relationship with the doctors and the care that will be provided.

In order to make an appropriate decision, we ask that you carefully read the following information:

OBJECTIVE AND METHODOLOGY OF THE STUDY

The aim of the study is to determine whether one anesthetic technique has fewer complications than the other, in terms of changes in blood pressure, blood oxygenation and heart rate.

The anesthetic techniques will be: one is to block the nerves that innervate the shoulder and sedation, and the other anesthetic technique is to block the nerves that innervate the shoulder and general anesthesia. The sedation will keep you asleep, but you may wake up during the procedure, but you will not feel pain, as your shoulder will be anesthetized. Under general anesthesia, you will sleep fully and wake up only at the end of the surgical procedure, completely losing consciousness.

The choice of one technique or another will be made randomly through a program. You will not be able to choose the anesthetic technique. However, if you feel a preference in some technique, you can discuss it with the doctor and not participate in the study.

Participants will be divided into two groups, in which each group will use a different anesthetic technique. Both groups will receive anesthesia for the surgery. Anesthesia of the shoulder nerves will be done with local anesthetic. During the surgery, if you feel any discomfort, the anesthetic technique will be modified for your best comfort.

After the surgery, we will monitor your case for 24 hours, regardless of the type of anesthesia used.

Therefore, it is necessary to sign the acceptance of participation in the study with the registration of all clinical data and evolution of your case.

RISKS AND BENEFITS

The two anesthetic techniques are already used normally for this surgery that you will have.

Below we explain the benefits and risks that are already reported in the current literature for the anesthetic technique related to your surgery.

Benefits

- The expected benefit is better measurement of blood pressure, heart rate and blood oxygen during surgery which can improve both long-term and short-term surgical outcomes.
- Determine the best anesthetic technique for this type of surgery that you, as a volunteer, will perform.

Scratches

Potential risks and complications include:

- No improvement in blood pressure, heart rate, blood oxygenation and brain measurements comparing the two anesthetic techniques.
- Change the anesthetic technique from sedation, if any discomfort occurs, to general anesthesia, however you will not experience pain or other uncomfortable symptoms during the change of anesthesia.
- Expose your clinical data to analyze the results.

FREE AND VOLUNTARY PARTICIPATION

Your participation is completely voluntary and will not incur additional costs to him/her if you agree to participate by signing the Free and Informed Consent Form.

If new information emerges during the study that may put your participation in doubt, you will be informed immediately.

If this is the case, and you or your legal guardian authorizes your family member or loved one to participate, you may also change your mind at any time, without justification, and your decision will not affect the quality of care for the illness.

In addition, if you accept to participate in the study, you will be treated in the same way as if you were outside the research, and you will receive all the necessary treatment to resolve your illness.

If you do not participate in the study, you will have your normal care according to the hospital's services, without any harm to you or your health care.

CONFIDENTIALITY

The personal data obtained will be those necessary to cover the purposes of the study. In none of the study reports will his name appear and his identity will not be revealed to any person, except to fulfill the objectives of the study and in the event of a medical emergency or legal requirement. Any information of a personal nature that may be identifiable will be kept by computer methods under secure conditions by the research team. Access to this information will be restricted to the research team. Under current law, you have the right to access your personal data; likewise, and if justified, you are entitled to its rectification and cancellation. If you wish, ask the doctor treating you in this study.

You can also access the general results of the study on request. In accordance with current legislation, you have the right to be informed of data relevant to your health obtained in the course of the study. This information will be communicated to you if you wish. If you prefer not to be informed, your decision will be respected.

ETHICAL CONSIDERATIONS

Registration will be carried out under the Declaration of Helsinki of the 64th World Medical Association. The study will be carried out following the rules of Good Clinical Practice.

This consent form is issued in two copies and must be signed by the participant and researcher in both copies. Each party involved will be responsible for keeping a copy of this document.

If the participant has any problem regarding this study, he/she will receive all assistance related to the problem at no cost.

This study was approved by the Research Ethics Committee of the Municipal Health Department of São Paulo. If you have any questions regarding the rights of research participants or regarding the ethical aspects involved, please feel free to contact the Ethics Committee, located at Rua Gomes de Carvalho, 250 Vila Olímpia – São Paulo, Monday. Friday from 10 am to 4 pm. Telephone: (11) 3846-4815 extensions 228, 242, 243 and e-mail: smscep@gmail.com.

The study team is available to provide any clarifications before, during and after the study. The study team is formed by the following professionals: Lia Alves Martins Mota Lustosa, Adilson Hamaji, Marcelo Waldir M Hamaji, Juliano Pinheiro de Almeida, Joao Manoel Silva Junior. The contact phone number is: (11) 955785500, anytime, 24 hours a day, 7 days a week.

After the explanations above and removing all your doubts, I invite you to participate in the project, if you accept to participate, sign below:

I, _____, declare that I have been informed and agree to participate, as a volunteer, in the research project described above.

São Paulo, _____ of _____ of _____.

Participant name and signature

Participant name and signature



SECRETARIA DE GOVERNO

Instituto de Assistência Médica ao Servidor Público Estadual
Cedep - Centro de Desenvolvimento de Ensino e Pesquisa
Avenida Ibirapuera, 981 - Vila Clementino - CEP: 04029-000 - Tel: 4573-8000



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INFORMED CONSENT FORM

Project Title: "HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL"

Responsible researcher: Pedro Hilton de Andrade Filho - Pertence a instituição: Hospital do Servidor Público Estadual (HSPE). CONTATO: Rua Pedro de Toledo, 1800 – Vila Clementino, São Paulo-SP. Telefone: 4573-8175

Volunteer Name: _____

Age: _____

R.G: _____

You are being invited to participate in the research project: **"HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL"**

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For some people who may have some type of disability that makes it impossible to make decisions for themselves, the legal guardian will be asked to decide to participate in the study, please read this informed consent form carefully.

WHY IS THIS CLINICAL STUDY CARRIED OUT?

Dear Mr. Mrs, you will undergo arthroscopy shoulder surgery.

There are two anesthetic techniques described for performing this procedure: general anesthesia + interscalene block and sedation + interscalene block.

Both techniques can be used normally for performing this type of surgery in the scientific community.

However, there are some reports that the sedation + block technique can generate fewer side effects, such as less blood pressure decrease and fewer complications resulting from the decrease in



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blood pressure. Since any anesthetic technique promotes hemodynamic changes, such as a decrease in blood pressure.

This option may offer greater care during the surgical procedure.

Below you will find information about this study, its role, risks, restrictions and benefits of your participation and the informed consent form.

You are free to accept or reject your participation in this registry; this does not change the quality of the relationship with the doctors and the care that will be provided.

In order to make an appropriate decision, we ask that you carefully read the following information:

OBJECTIVE AND METHODOLOGY OF THE STUDY

The aim of the study is to determine whether one anesthetic technique has fewer side effects than another, in terms of blood pressure, O₂ saturation and pain.

The anesthetic techniques will be: one is to block the nerves that innervate the shoulder and sedation, and the other anesthetic technique is to block the nerves that innervate the shoulder and general anesthesia. The sedation will keep you asleep, but you may wake up during the procedure, but you will not feel pain, as your shoulder will be anesthetized. Under general anesthesia, you will sleep fully and wake up only at the end of the surgical procedure. Patients will be divided into two groups, in which each group will use a different anesthetic technique. Both groups will receive anesthesia for the surgical procedure. Anesthesia of the shoulder nerves will be done with local anesthesia. During the procedure, if you feel any discomfort, the anesthetic technique will be modified for your best comfort during the surgical procedure.

After the surgery, all patients who were part of the study will be followed up for 24 hours for independent evaluation of the type of anesthesia used.

Therefore, it is necessary to sign the acceptance of participation in the study with the registration of all clinical data and evolution of your case.

RISKS AND BENEFITS

Benefits

The benefit that can be expected is, perhaps, better measurement of blood pressure, heart rate and oxygen saturation during surgery which can improve long-term and short-term surgical outcomes.

Potential risks and complications include:

- No improvement in blood pressure, heart rate, and oxygen saturation measurements.



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- Changing the anesthetic technique from sedation to general anesthesia, however you would not experience pain or other uncomfortable symptoms during the change from anesthesia.

FREE AND VOLUNTARY PARTICIPATION

Your participation is completely voluntary and will not incur additional costs to him/her if you agree to participate by signing the Free and Informed Consent Form.

If new information emerges during the study that may put your participation in doubt, you will be informed immediately.

If this is the case, and you authorize your family member or loved one to participate, you may also change your mind at any time, without justification, and your decision will not affect the quality of treatment of the patient's illness.

In addition, if you accept to participate in the study, you will be treated in the same way as if you were outside the research, and you will receive all the necessary treatment to resolve your illness.

If you do not participate in the study, you will have your normal care according to the hospital's services, without any harm to you or your health care.

CONFIDENTIALITY

The personal data obtained will be those necessary to cover the purposes of the study. In none of the study reports will his name appear and his identity will not be revealed to any person, except to fulfill the objectives of the study and in the event of a medical emergency or legal requirement. Any information of a personal nature that may be identifiable will be kept by computer methods under secure conditions by the research team. Access to this information will be restricted to the research team. Under current law, you have the right to access your personal data; Likewise, and if justified, you are entitled to its rectification and cancellation. If you wish, ask the doctor treating you in this study.

You can also access the general results of the study on request. In accordance with current legislation, you have the right to be informed of data relevant to your health obtained in the course of the study. This information will be communicated to you if you wish; If you prefer not to be informed, your decision will be respected.

ETHICAL CONSIDERATIONS

Registration will be carried out under the Declaration of Helsinki of the 64th World Medical Association. The study will be carried out following the rules of Good Clinical Practice.

This consent form is issued in two copies and must be signed by the participant and researcher in both copies. Each party involved will be responsible for keeping a copy of this document.



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This study was approved by the Research Ethics Committee of the Hospital do Servidor Público Estadual de São Paulo, São Paulo – SP. If you have any questions regarding the rights of research participants or regarding the ethical aspects involved, feel free to contact the Research Ethics Committee of the Hospital do Servidor Público Estadual de São Paulo, located at Av. Ibirapuera, 981, 1º andar, Sala 106, São Paulo – SP, by phone (11) 4573-8175 or by e-mail: cepiamspe@iamspe.sp.gov.br.

The study team is available to provide any clarifications before, during and after the study at the following telephone numbers: Lia Alves Martins Mota Lustosa: (11) 955785500, at any time, 24 hours a day, 7 days a week.

I, _____, ID no. _____, declare that I have been informed and agree to participate, as a volunteer, in the research project described above.

São Paulo, ____ of ____ of ____.

Participant name and signature

Participant name and signature

**HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION
PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL**

Lia Alves Martins Mota Lustosa

Advisor: Prof. Dr. João Manoel Silva Júnior

São Paulo

06/29/2022

**CLINICAL HOSPITAL - INSTITUTE OF ORTHOPEDIA AND TRAUMATOLOGY OF THE
FACULTY OF MEDICINE OF THE UNIVERSITY OF SÃO PAULO - HCFMUSP**

INFORMED CONSENT FORM

DATES ABOUT RESEARCH

1. TITLE: HEMODYNAMIC AND CEREBRAL EFFECT OF GENERAL ANESTHESIA PLUS BLOCK INTERESCALENIC vs SEDATION PLUS BLOCK INTERESCALENIC: THE RECOGNISED RANDOMIZED CONTROLLED TRIAL

2. RESPONSIBLE RESEARCHER: Lia Alves Martins Mota Lustosa

POSITION/FUNCTION: Anesthesiologist Physician

REGIONAL COUNCIL REGISTRATION No. 179.500

3. UNIT OF HCFMUSP: Department of Surgery; ICHC-FMUSP Anesthesia Division

**CLINICAL HOSPITAL - INSTITUTE OF ORTHOPEDIA AND TRAUMATOLOGY OF THE
FACULTY OF MEDICINE OF THE UNIVERSITY OF SÃO PAULO - HCFMUSP**

1 – You are being invited to participate in a clinical research where we are going to study two anesthetic techniques for shoulder arthroscopy surgeries, these anesthetic techniques are already used normally during the procedures.

2 – The objective of the study is to determine whether an anesthetic technique has fewer side effects than another, in relation to blood pressure, O2 saturation and pain.

3 – The anesthetic techniques will be: one is to block the nerves that innervate the shoulder and sedation, and the other anesthetic technique is to block the nerves that innervate the shoulder and general anesthesia. The sedation will keep you asleep, but you may wake up during the procedure, but you will not feel pain, as your shoulder will be anesthetized. Under general anesthesia, you will sleep fully and wake up only at the end of the surgical procedure. Patients will be divided into two groups, in which each group will use a different anesthetic technique. Both groups will receive anesthesia for the surgical procedure. Anesthesia of the shoulder nerves will be done with local anesthesia. During the procedure, if you feel any discomfort, the anesthetic technique will be modified for your best comfort during the surgical procedure.

4 – If you participate in the study, your care will be done in the same way as if you were outside the research, and you will receive all the necessary treatment for the resolution of your disease.

5 – Anesthesia discomfort would be the need to change anesthesia from sedation to general anesthesia, however you would not experience pain or other uncomfortable symptoms during the change of anesthesia.

6 – The benefit that can be expected is, perhaps, better measurement of blood pressure, heart rate and oxygen saturation during surgery.

7 – After the surgery, all patients who were part of the study will be followed up for 24 hours for independent evaluation of the type of anesthesia used.

8 – If you do not participate in the study, you will have your normal care according to the conduct of the hospital services, without any harm to you or your health care.

9 – At any stage of the study, you will have access to the professionals responsible for the research to clarify any doubts. The principal investigator is Dr. Lia Alves Martins Mota Lustosa which can be found at the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo – Institute of Orthopedics and Traumatology at Rua Ovidio Pires de Campos – 333 – Cerqueira César - 05403-000 / São Paulo - Brazil telephone : 32661-6655. If you have any concerns or questions about research ethics, please contact the Research Ethics Committee (CEP) – Rua Ovídio Pires de Campos, 255 – 5º andar – tel: (11) 2661-7585, (11) 2661-1548, (11) 26611549; e-mail: cappelq.adm@hc.fm.usp.br.

10 – At any time during the study, you will be free to withdraw consent and may stop participating in the study, without any prejudice to the continuity of your treatment at the Institution.

11 – The information obtained will be analyzed together with data from other patients, the identification of any patient will not be disclosed and will later be archived in a secure database.

12 – Patients participating in the study will not have any expenses in any phase of the study, including hospitalization, exams, surgeries and consultations. They will also not receive financial compensation related to their participation.

13 – Research participants will receive a copy of this document for future reference.

14 – The study researchers undertake to use the data and material collected only for that research, with all data being archived after the end and analysis of the results.

**CLINICAL HOSPITAL - INSTITUTE OF ORTHOPEDIA AND TRAUMATOLOGY OF THE
FACULTY OF MEDICINE OF THE UNIVERSITY OF SÃO PAULO - HCFMUSP**

I believe I have been sufficiently informed about the information that I read or that was read to me, describing the study on anesthesia techniques for shoulder arthroscopy surgeries.

I discussed with Dr. Lia Alves Martins Mota Lustosa about my decision to participate in this study. It was clear to me what the purposes of the study are, the procedures to be carried out, their discomforts and risks, the guarantees of confidentiality and permanent clarification. It was also clear that my participation is free of charge and that I am guaranteed access to hospital treatment when necessary. I voluntarily agree to participate in this study and may withdraw my consent at any time, before or during the study, without penalty or detriment or loss of any benefit that I may have acquired from, or in my attendance at, this Service. I sign this consent form and receive a copy initialed by the researcher.

Signature of the participant/legal
representative

Data ____ / ____ / ____

Name of participant/legal representative

Data ____ / ____ / ____

(Only for the project manager)

I declare that I have properly and voluntarily obtained the Free and Informed Consent from this patient or legal representative to participate in this study.

Signature of the person responsible for the

study

Data ____ / ____ / ____