Sphenopalatine nerve block for postoperative analgesia in transsphenoidal approaches: a prospective, randomized and double-blind study.

Informed Consent Form

NCT number: XXXXXXXXX

11/09/2019

INFORMED CONSENT FORM

You are being invited to participate in the research: Blocking the sphenopalatine nerve ganglion for postoperative analgesia in transsphenoidal accesses: prospective, randomized and double-blind study

Any patient who is a candidate for surgery to remove the lesion inside the head from inside the nose aged between 18 and 64 years, who meets the criteria established by the research team, will be invited to participate in this study. In order for you to decide whether you want to participate or not, you need to know its benefits, risks and implications.

OBJECTIVE OF THE STUDY

We will place a cotton swab with anesthetic, close to a nerve, which is close to the surgery site. After that we will see if you will be better and without pain after the surgical procedure.

PROCEDURE

If you agree to participate in the research, you will receive visits by the research team between 2, 6, 12 and 24 h after the end of the surgery. During visits you will answer questions about your pain after surgery. The researcher will show you a kind of ruler, with pictures that help show him how much pain you are feeling. It is important that you know that your privacy is fully guaranteed.

OPTION

The alternative will be your refusal to participate in the research.

RISKS

There is no increase in any risk due to your acceptance to participate in the study. The risks are the same as for any patient undergoing general anesthesia. They will be clarified during the pre-anesthetic visit.

BENEFITS

Less pain after surgery.

MONITORING, ASSISTANCE AND RESPONSIBLE

The person responsible for the study is Dr. Brynner Mota Buçard, an anesthesiologist at the Instituto Estadual do Cérebro Paulo Niemeyer , who can provide any clarification on the study at any time.

COSTS

There will be no expense or payment for the patient for participating in the study.

BASIS OF PARTICIPATION

It is important that you know that your participation in this study is completely voluntary and that you can refuse to participate or stop your participation at any time, without any problems or loss of benefits to which you are entitled. In case you decide not to participate in the study anymore, the research team must be notified and all your information will be removed from the research.

CLARIFICATION GUARANTEE

We encourage you or your family to ask questions at any time during the study. In this case, contact Dr. Brynner Mota Buçard at (32) 99943-5055 or email: probrynner@hotmail.com. If you have questions regarding your rights as a study participant, you can also have impartial contact from the Research Ethics Committee of the Instituto Estadual do Cérebro Paulo Niemeyer, located at Av. Washington Luiz, 47, Centro, Rio de Janeiro / RJ - CEP: 20.231-092; by phone: (21) 2277 - 9330 / (21) 2277-9449; e-mail: cep@iecpnprosaude.org.br.

STATEMENT BY THE PARTICIPANT

I read the information above and understood the purpose of this study, as well as the potential benefits and risks of my participation. I had the opportunity to ask questions and they were all answered. Through this document, I freely give my authorization to participate in this study.

I understand that I will not receive monetary compensation for my participation in this study.

I received a signed copy of this consent form.

_____

(Name of research subject)

_____ ____ / ____ / ____

(Signature of the research subject)

_____ ____ /__/____

(Signature of principal investigator)