

ANNEX IV. INFORMED CONSENT FORM FOR PARTICIPATION IN RESEARCH PROTOCOLS

(Parents or legal representatives of children or persons with disability)

MEXICAN SOCIAL SECURITY INSTITUTE

Unit of Education, Research and Health Policies

Research Coordination

Informed consent form for participation in research protocols (parents or legal representatives of children or persons with disability).

Item	Information
Study title	Efficacy and safety of central venous catheter placement in the internal jugular vein using ultrasound-guided technique versus anatomical landmark technique in critically ill paediatric patients: a randomised clinical trial.
External sponsor (if applicable)	Not applicable.
Place and date	
Registration number	R-2019.1002-028.

Justification and objective of the study

Your child needs a small plastic tube, called a central venous catheter, to be placed in a vein in the neck. This tube is very useful for administering different medicines and fluids as part of treatment because your child is very ill, that is, critically ill, and this is the most effective way to administer urgent treatment. We would like to ask for your authorisation for your child to take part in a study in which this tube was placed in one of two ways. The first consisted of puncturing the vein in the neck using the pulse felt in the neck and the muscles surrounding the vein as a guide, in order to place the plastic tube in the vein. The second consisted of using ultrasound to help visualise the vein and then puncturing the vein to insert the plastic tube. We wanted to identify which puncture technique was better so that, in the future, the technique offering the greatest benefit for children could be used. If you agree for your child to participate, he or she will belong to only one study group; that is, only one method of puncturing the neck vein will be used to place the plastic tube.

Procedures

Puncture one: the doctor cleans the child's neck thoroughly. The doctor performing the puncture wears clean sterile clothing so that everything remains clean. The doctor then punctures the vein in the neck and inserts the plastic tube, called a central venous catheter.

Puncture two: the doctor cleans the child's neck thoroughly. The doctor performing the puncture wears clean sterile clothing so that everything remains clean. The doctor uses an ultrasound

machine, which is also kept sterile, to see the vein that will be punctured. The doctor then punctures the neck and inserts the plastic tube, called a central venous catheter.

Possible risks and discomforts

The risks for both types of puncture are the same whenever the plastic tube, called a central venous catheter, is placed. This tube, which your child needs in order to receive medicines and fluids, may be associated with problems during placement. The vein may be punctured and this may cause bruising and swelling at the puncture site. The puncture may injure the lung, veins or arteries. Because your child is critically ill, the heart may also be affected, causing palpitations or even causing the heart to stop beating. Arrhythmias and infections may also occur. If any complication related to either of the two puncture techniques occurs, the necessary resources are available to resolve any type of complication promptly. These complications are uncommon, but they may occur.

Possible benefits of taking part in the study

Placement of the plastic tube, called a central venous catheter, is a very common practice and forms part of the treatment of critically ill patients, who may require administration of fluids, medicines, transfusions and parenteral nutrition, as well as rapid measurement of blood pressure. High-quality and compassionate medical care will be provided at all times.

Information on results and treatment alternatives

The alternative to this procedure is to cannulate a vein in an arm or leg, known as a peripheral vein, to administer medicines and fluids. However, these veins are not suitable for certain medicines and fluids that need to be administered through a larger vein, known as a central vein. These include some medicines that act directly on the heart, known as vasoactive medicines, and other medicines used in intensive care that must be administered through large-calibre veins. Otherwise, if administered through veins in an arm or leg, these medicines may cause inflammation, injury and burns in the peripheral vein; this does not occur in the same way when they are administered through a large-calibre vein, known as a central vein. The result of placing the plastic tube in the vein, called a central venous catheter, may be successful or unsuccessful. If placement is unsuccessful, that is, if the catheter cannot be placed, another site will be sought so that the patient can receive treatment. If the plastic tube, called a central venous catheter, cannot be placed using either of the two puncture techniques described above, a venous cut-down will be performed; this consists of locating the vein directly through a small incision.

Participation or withdrawal

Medical care will always be of high quality and compassionate, whether or not the patient participates in the research protocol. Any questions that may arise during the protocol will be answered at all times. If you wish, you may withdraw from the protocol without affecting the patient's medical care, and the decision of the responsible person or legal guardian will be respected.

Privacy and confidentiality

The privacy and confidentiality of the patient, father, mother or legal guardian will be respected at all times. The participant will not be identified in any presentations or publications derived from this study.

Consent statement

After having read this information and having had all my questions about this study explained to me:

☐ I do not agree for my relative or represented person to take part in the study.

☐ I agree for my relative or represented person to take part and for the sample to be taken only for this study.

☐ I agree for my relative or represented person to take part and for the sample to be taken for this study and future studies, with his or her blood stored for up to ____ years, after which it will be destroyed.

Contacts for questions or clarifications related to the study

Responsible investigator: Gloria Patricia Sosa Bustamante

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Collaborators: Dr Israel Sinahi Moreno Aguirre;

Questions or clarifications regarding participant rights

For questions or clarifications regarding your rights as a participant, you may contact the IMSS CNIC Research Ethics Committee: Avenida Cuauhtémoc 330, 4th floor, Block "B", Congress Unit, Colonia

Doctores, Mexico City, CP 06720. Telephone: (55) 56 27 69 00 extension 21230. Email: comision.etica@imss.gob.mx

Name and signature of both parents, guardians or legal representative

Name and signature of the person obtaining consent

Witness 1: _____

Name and signature of the person obtaining consent

Witness 2: _____

Name, address, relationship and signature

This form constitutes a guide that must be completed according to the specific characteristics of each research protocol, without omitting relevant study information.

* If external sponsorship is available, the protocol must be evaluated by the National Scientific Research Commission.

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