|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| IMSSN | | | | | **MEXICAN INSTITUTE OF SOCIAL SECURITY**  **EDUCATION, RESEARCH AND HEALTH POLICIES UNIT**  **HEALTH RESEARCH COORDINATION**  **INFORMED CONSENT**  **(ADULTS)** | | |
| INFORMED CONSENT FOR PATICIPATION IN TRIALS | | | | | | | | |
| Name of the trial: | | Comparison of the anesthetic effect of different dosages of tetracaine 0.5% ophthalmic solution on corneal sensation | | | | | | |
| External sponsors (if any) | | No external sponsors involved. | | | | | | |
| Date and place: | | Mérida, Yucatán, (day/ month/ year) | | | | | | |
| Registry number: | | R-2019-3202-05 | | | | | | |
| Justification and objective of the trial: | | To find out how long does the maximum effect of tetracaine 0.5% last (anesthetic medication routinely used in ophthalmology) at different doses on the cornea (the superficial clear front part of the eye) in order to be able to anticipate the desired effect depending on the planned procedure, and to avoid uncomfortable sensations at any moment. | | | | | | |
| Procedure: | | Corneal esthesiometry with Cochet-Bonnet esthesiometer under local anesthesia with tetracaine 0.5% ophthalmic solution. It consists on appling a stimulus with a nylon fiber at different lengths, before and after medication instillation, every 3 minutes until normal corneal sensitivity is recovered, or after 63 minutes top. We will ask you to verbally express the moment you feel the stimulus in your cornea. | | | | | | |
| Possible risks and harms: | | Risks are mainly those derived from tetracaine. Corneal epithelium (most superficial layer of the cornea) can suffer abrasion if the subject rub his eyes while being under the effect of the anesthetic resulting later in pain, tearing and discomfort with light. To avoid this, please do not rub or touch your eyes at least one hour after the procedure. Corneal anesthesia can decrease blinking frequency and tearing, thus causing blurred vision that improves with blinking. This adverse effect is self-limited when the effect of the tetracaine ends. Tetracaine drop application can produce burning sensation during approximately 30 seconds. Adverse effects are rare and include eyelid swelling, redness, and posteriorly itch and irritation that can last for a few days. Severe adverse effects such as corneal ulcers and perforation have been noted to occur only in cases of tetracaine abuse, and have never been reported at the doses handled in this trial. Esthesiometry itself, is the measurement of corneal sensitivity to a known pressure, applied with a nylon fiber. The contact of this fiber with the cornea can produce a slight discomfort sensation. Although we have not found any adverse event due to the esthesiometry, we could expect corneal abrasion (described earlier) that heals in a 24 to 48 hours period. An infection called keratitis can overcome a corneal abrasion. It is characterized by pain, redness, blurred visión, tearing, spasm of the eyelids, discomfort with light, secretion, and severe cases can lead to sequelae such as decreased vision, scars in the cornea, or in the worst-case eye loss. To avoid this, the esthesiometer will be desinfected among patients, and a single drop of topical antibiotic will be applied to every patient. For the detection of corneal abrasion, after the procedure we will use a fluoresceine dye strip. In case it was found, topical antibiotic will be applied every 4 hours to prevent infection, and a new visit will be provided 24 hours later to repeat fluorescein dye, and so on every 24 hours until the abrasion heals. If needed, the antibiotics will be provided by the research group. | | | | | | |
| Possible benefits from pariticipating in this trial | | As part of the protocol, we will perform an ophthalmic assessment which includes visual acuity measurement, physical exploration on the slit lamp of ocular adnexa, anterior segment and fundus. This serves as a screening for possible ocular pathologies that the subject could be unaware of, and it represents a direct benefit for the patient. No chardsges will be applied. As an indirect benefit, we will generate information on the optimal tetracaine dose, as it is a frequently used drug for many diagnostic and therapeutic procedures. | | | | | | |
| Information about results and treatment alternatives | | A printed copy of the initial assessment will be handed to the patient. In case of any ophthalmic pathology detection, the subject will not be eligible to participate in the trial. Treatment prescription and complementary diagnostic tests are not offered by this research group for pathologies detected on the initial assessment. | | | | | | |
| Participation or retreat: | | The subject is free to decide whether to participate or not on the trial and can ask to abandon the test at any moment. Any question can be solved by the enlisted authors. | | | | | | |
| Privacy and confidentiality | | The results from the trial are intended to be published on scientific journals. The authors are committed to maintain the subject’s identity private, and do not unveil it in any publications. In case the subject agrees, the compiled data can be used for future studies. | | | | | | |
| In case of biologic material collection (if applies): | | | | | | | | |
|  | I do not authorize sampling. | | | | | | | |
|  | I do authorize sampling for this study. | | | | | | | |
|  | I do authorize sampling for this and future studies. | | | | | | | |
| Medical treatment availability for insured patients (if applies) | | | | | | It does not apply. | | |
| Benefits at the end of the trial: | | | | A copy of the initial assessment will be handed to the subject. If the subject requests it, a copy of the results from the esthesiometry can be supplied. | | | | |
| In case of doubts or questions related to the study, please address to: | | | | | | | | |
| Responsible researcher: | | | Ricardo Navarro Saucedo (first author) / Matrícula 98333647/ Third year ophthalmology resdient/ Hospital General Regional No. 12 Benito Juárez/ IMSS/ Phone number 4731417049 | | | | | |
| Collaborators: | | | Diego Antonio Solórzano Ugalde (coauthor)/ Anterior segment subspecialist, Ophthalmologist surgeon, working in the ophthalmology department at HGR No. 12 Benito Juárez, IMSS; and main professor of the specialty at the Autonomous University of Yucatán, campus HGR No 12 Benito Juárez, IMSS. | | | | | |
| In case of doubts or questions about your rights please address to: Ethics on Research Committee of the CNIC from the IMSS: Avenida Cuauhtémoc 330 4° piso Bloque “B” de la Unidad de Congresos, Colonia Doctores. México, D.F., CP 06720. Phone number (55) 56 27 69 00 extension 21230, e-mail address: [comision.etica@imss.gob.mx](mailto:comision.etica@imss.gob.mx) | | | | | | | | |
| Subject’s name and signature | | | | | | | **Ricardo Navarro Saucedo/ Matrícula 98333647**  Name of the person obtaining the consent | |
| Witness 1  Name, address, relationship to the subject and signature | | | | | | | Witness 2  Name, address, relationship to the person and signature | |
|  | | | | | | | | |
| **Clave: 2810-009-013** | | | | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| IMSSN | | | | **MEXICAN INSTITUTE OF SOCIAL SECURITY**  **EDUCATION, RESEARCH AND HEALTH POLICIES UNIT**  **HEALTH RESEARCH COORDINATION**  **INFORMED CONSENT TO PARTICIPATE OON RESEARCH STUDIES**  **(LEGAL REPRESENTATIVE FOR SUBJECTS WITH A DISABILITY)** | |  |
| Name of the trial: | | Comparison of the anesthetic effect of different dosages of tetracaine 0.5% ophthalmic solution on corneal sensation | | | | |
| External sponsors (if any) | | No external sponsors involved. | | | | |
| Date and place: | | Mérida, Yucatán, (day/ month/ year) | | | | |
| Registry number: | | R-2019-3202-05 | | | | |
| Justification and objective of the trial: | | To find out how long does the maximum effect of tetracaine 0.5% last (anesthetic medication routinely used in ophthalmology) at different doses on the cornea (the superficial clear front part of the eye) in order to be able to anticipate the desired effect depending on the planned procedure, and to avoid uncomfortable sensations at any moment. | | | | |
| Procedure: | | If the subject’s disability affects the patient’s capability to respond to the stimulus on the cornea, or if the person cannot understand or follow instructions, then he or she is not eligible to participate in this study. Corneal esthesiometry with Cochet-Bonnet esthesiometer under local anesthesia with tetracaine 0.5% ophthalmic solution. It consists on appling a stimulus with a nylon fiber at different lengths, before and after medication instillation, every 3 minutes until normal corneal sensitivity is recovered, or after 63 minutes top. We will ask you to verbally express the moment you feel the stimulus in your cornea. | | | | |
| Possible risks and harms: | | Risks are mainly those derived from tetracaine. Corneal epithelium (most superficial layer of the cornea) can suffer abrasion if the subject rub his eyes while being under the effect of the anesthetic resulting later in pain, tearing and discomfort with light. To avoid this, please do not rub or touch your eyes at least one hour after the procedure. Corneal anesthesia can decrease blinking frequency and tearing, thus causing blurred vision that improves with blinking. This adverse effect is self-limited when the effect of the tetracaine ends. Tetracaine drop application can produce burning sensation during approximately 30 seconds. Adverse effects are rare and include eyelid swelling, redness, and posteriorly itch and irritation that can last for a few days. Severe adverse effects such as corneal ulcers and perforation have been noted to occur only in cases of tetracaine abuse, and have never been reported at the doses handled in this trial. Esthesiometry itself, is the measurement of corneal sensitivity to a known pressure, applied with a nylon fiber. The contact of this fiber with the cornea can produce a slight discomfort sensation. Although we have not found any adverse event due to the esthesiometry, we could expect corneal abrasion (described earlier) that heals in a 24 to 48 hours period. An infection called keratitis can overcome a corneal abrasion. It is characterized by pain, redness, blurred visión, tearing, spasm of the eyelids, discomfort with light, secretion, and severe cases can lead to sequelae such as decreased vision, scars in the cornea, or in the worst-case eye loss. To avoid this, the esthesiometer will be desinfected among patients, and a single drop of topical antibiotic will be applied to every patient. For the detection of corneal abrasion, after the procedure we will use a fluoresceine dye strip. In case it was found, topical antibiotic will be applied every 4 hours to prevent infection, and a new visit will be provided 24 hours later to repeat fluorescein dye, and so on every 24 hours until the abrasion heals. If needed, the antibiotics will be provided by the research group. | | | | |
| Possible benefits from pariticipating in this trial | | As part of the protocol, we will perform an ophthalmic assessment which includes visual acuity measurement, physical exploration on the slit lamp of ocular adnexa, anterior segment and fundus. This serves as a screening for possible ocular pathologies that the subject could be unaware of, and it represents a direct benefit for the patient. No chardsges will be applied. As an indirect benefit, we will generate information on the optimal tetracaine dose, as it is a frequently used drug for many diagnostic and therapeutic procedures. | | | | |
| Information about results and treatment alternatives | | A printed copy of the initial assessment will be handed to the patient. In case of any ophthalmic pathology detection, the subject will not be eligible to participate in the trial. Treatment prescription and complementary diagnostic tests are not offered by this research group for pathologies detected on the initial assessment. | | | | |
| Participation or retreat: | | The subject is free to decide whether to participate or not on the trial and can ask to abandon the test at any moment. Any question can be solved by the enlisted authors. | | | | |
| Privacy and confidentiality | | The results from the trial are intended to be published on scientific journals. The authors are committed to maintain the subject’s identity private, and do not unveil it in any publications. In case the subject agrees, the compiled data can be used for future studies. | | | | |
| **Consent declaration** | | | | | | |
| After reading and solving every doubt about this study: | | | | | | |
|  | I do not agree that my relative or represented participate in this study. | | | | | |
|  | I agree that my relative or represented participates in this study, and I also authorize sampling only for this study. | | | | | |
|  | I agree that my relative or represented participates in this study, and I also authorize sampling for this study and future studies, storing his or heer blood sample up to \_\_ years after which it will be destroyed. | | | | | |
|  | | | | | | |
| **In case of doubts or questions related to the study, please address to:** | | | | | | |
| Responsible researcher: | | | Ricardo Navarro Saucedo (first author) / Matrícula 98333647/ Third year ophthalmology resdient/ Hospital General Regional No. 12 Benito Juárez/ IMSS/ Phone number 4731417049 | | | |
| Collaborators: | | | Diego Antonio Solórzano Ugalde (coauthor)/ Anterior segment subspecialist, Ophthalmologist surgeon, working in the ophthalmology department at HGR No. 12 Benito Juárez, IMSS; and main professor of the specialty at the Autonomous University of Yucatán, campus HGR No 12 Benito Juárez, IMSS. | | | |
| In case of doubts or questions about your rights please address to: Ethics on Research Committee of the CNIC from the IMSS: Avenida Cuauhtémoc 330 4° piso Bloque “B” de la Unidad de Congresos, Colonia Doctores. México, D.F., CP 06720. Phone number (55) 56 27 69 00 extension 21230, e-mail address: [comité.eticainv@imss.gob.mx](mailto:comité.eticainv@imss.gob.mx)  If during the study you identify or percieve any discomfort, pain, irritation or changes in the skin caused by the sampling or drug application, you can address to: Drug Vigilance Area, phone number: (55) 56276900, ext. 21222, e-mail adress: [iris.contreras@imss.gob.mx](mailto:iris.contreras@imss.gob.mx) | | | | | | |
| Name and signature of both parents or tutors or legal representatives | | | | | Name of the person obtaining the consent | |
| Witness 1  Name, address, relationship to the subject and signature | | | | | Witness 2  Name, address, relationship to the person and signature | |
| **Clave: 2810-009-014**  **1 de 2** | | | | | | |