CHRONIC POSTSURGICAL PEDIATRIC PAIN.

TITLE: RISK FACTORS TO DEVELOP CHRONIC POSTSURGICAL PEDIATRIC PAIN

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PROJECT ENTITIES: COMPLUTENSE UNIVERSITY OF MADRID & 12 OCTUBRE PEDIATRIC HOSPITAL.

NUMBER OF IDENTIFIACTION: 26/618

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STUDY PROTOCOL

Type of Study: Observational longitudinal prospective. The study has approved by etic comity of clinical research of Hospital 12 de octubre de madrid.

Target population: Pediatric population undergoing surgery intervention in 12 de octubre hospital.

Sample: A convenience sampling will be carried out among the patients undergoing surgical intervention according eligibility criteria.

- **Inclusion criteria:** Children with age from 4 years to 18 years. Undergoing surgery for any surgical specialty. ASA Status (American Society of Anesthesiologist) from I to III.
- **Exclusion Criteria:** Children who do not understated and speak Spanish correctly. Children with verbal communication problems.
- **Stratification of the sample:** The sample will be divided into 2 sample groups: a) children into 4 to 8 years, and b) children into 8 to 18 years.
- **Sample size:** To assess the degree of association between the different clinical variables and the development of chronic postsurgical pain in the pediatric population, the calculation of the sample size was based on previous literature that proposes 20 cases per variable in order to estimate a prediction model in a relatively stable manner. Therefore, taking into account that a total of 13 predictor variables were used (anxiety, catastrophism, fear of pain, fear of movement, pain interference, disability, limitation of activities, prediction of chronic pain in children and

catastrophism, anxiety, fear of pain, fear of movement of parents / guardians / companions), it was considered necessary to include at least 260 children undergoing surgery to meet the objective of this study

Study design.

- On the day of admission to the pediatric surgery service of the hospital, the potential participant and parents of the study in progress will be informed. First, patients and parents will be informed about the possibility of voluntary participation in the study. Next, the objective, process and potential benefits of this will be reported. The consent of the legal guardians will then be requested. They will be asked to fill in the information of the demographic and clinical variables, answering the self-assessment instruments (the data collection will have an estimated time of 30 'per subject), both children and parents / companions. After the surgical intervention and within a period comprised in the first 5 days, an evaluation of the dependent variables (intensity, location and distribution of pain) will be carried out in both children and parents. They should fill in the self-assessment instruments in the same way as in the pre-surgery session (this will take approximately 10 minutes).
- At 10 days, 3 months, 6 months and 12 months after the intervention, will contact the patients and relatives by telephone, and they will be asked to reply again to the evaluation of all the variables. The evaluation will be carried out by telephone interview.
- The information sheet, the informed consent, and the evaluation instruments will be collected by a researcher, stored and guarded in the Department of Radiology, Rehabilitation and Physiotherapy of the Complutense University of Madrid. Thus, complying with the provisions of Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights.

Ethical Aspects

The study has the approval of the research commission of the Faculty of Nursing, Physiotherapy and Podiatry of the Complutense University of Madrid. Also, with the favorable opinion of the research commission of the Hospital 12 de Octubre Research Institute (i + 12). Lastly, it will be evaluated by the Ethics Committee of the research institute Hospital Universitario 12 de Octubre de Madrid (1 + 12).

The study will comply with all the ethical principles of the Declaration of Helsinki. All participants will participate in the study on a voluntary basis. They will be informed of the objective of the study, the procedure, and the process of carrying it out. In addition, the informed consent of each participant and their guardians will be required, which may be revoked at any time. In addition, they are within their right to know the results of the investigation once it has been completed.

The clinical and personal information will be totally confidential where the researchers will comply with the confidentiality commitments of the hospital center and the Faculty of Nursing, Physiotherapy and Podiatry. The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of the General Regulations for the Protection of Personal Data (Regulation 2016/679 of the European Parliament) and Organic Law 3 / 2018, of December 5, Protection of Personal Data and guarantee of digital rights.

The study does not hinder, modify, or interfere with routine clinical practice. Nor does it modify the service care protocols. The time of data collection is estimated at 30`. This time is not excessive for patients and their families and can provide

very relevant research and clinical information in order to understand the mechanisms of chronic pain in the pediatric population. This could save on medical care after the intervention, shortening the periods of hospitalization and readmission.

Therefore, it is considered that carrying out the study complies with the ethical and research standards and that the benefits in knowledge in the field that can be derived from it could significantly improve the healthcare activity, not assuming the realization of this, a serious damage to patients, families or professionals.