Hematological changes associated with the use of dipyrone versus paracetamol after dental extractions: a double-blind randomized clinical trial.

NCT07918040

14/09/2026

INFORMED CONSENT FORM

We would like to invite you to participate voluntarily in the research study entitled "HEMATOLOGICAL CHANGES ASSOCIATED WITH THE USE OF DIPYRONE VERSUS PARACETAMOL AFTER DENTAL EXTRACTIONS: A DOUBLE-BLIND RANDOMIZED CLINICAL TRIAL." The purpose of this study is to compare the effects of dipyrone and paracetamol on the blood of healthy patients, so that dentists can choose the safest analgesic for the postoperative period. In this study, we intend to evaluate and compare the effects of both medications on your blood tests (complete blood count and liver and kidney function tests) and monitor possible adverse reactions after tooth extraction, in order to determine which medication is safer in dental practice.

If you agree to participate, the following procedures will be carried out: you will undergo two simple tooth extractions (one during each study period), receive two medications (dipyrone 500 mg or paracetamol 750 mg) in a random order (determined by drawing lots), and undergo three blood collections. The teeth extracted will be only those for which extraction has already been indicated, and the medications used (dipyrone and paracetamol) are commonly prescribed after tooth removal. Neither you nor the researcher will know which medication is being used during each period, in order to avoid influencing the results. During the first period, you will attend a consultation and have the first blood sample collected. You will then undergo the first tooth extraction and receive one of the medications to take for 7 days. On the 8th day after the extraction, you will have a second blood sample collected. After at least 21 days, the second period will begin, during which you will undergo the second tooth extraction and receive the other medication to take for 7 days. On the 8th day after the second extraction, the third and final blood sample will be collected. Thus, three laboratory blood collections are planned throughout the study protocol. Blood samples may be collected at your home by a properly trained team from the laboratory responsible for the tests or, when necessary, you may be asked to travel to the laboratory for sample collection. If sample collection is not performed at your home, you may need to travel to the laboratory on up to three occasions during the study, corresponding to the three planned collections. Your transportation expenses will be reimbursed, and you will not incur any financial costs.

During each study period, you must take 2 capsules of the medication every 6 hours for 7 days. In addition, you will receive a postoperative form to complete at home, in which you must record the time the anesthesia wears off, the times you take the analgesic tablets, and the intensity of your pain immediately after surgery and at the following time points: 2, 24, 48, 72, 96, 120, 144, and 168 hours after surgery. You must also record any possible side effects (undesirable effects) related to the use of the medications. Throughout the study, the researchers responsible will monitor you through telephone calls and scheduled clinical assessments, as well as the follow-up visit planned for the 7th postoperative day of each period, in order to monitor the occurrence of possible adverse events and ensure appropriate care whenever necessary. If you experience side effects,

Participant or legally authorized representative's initials: _____
Researcher's initials: _____

you must immediately contact the researcher responsible, stop taking the study medication, and, if necessary, seek care at the nearest Emergency Care Unit (UPA) or at the Emergency Hospital (HPS) in Juiz de Fora.

This study involves some foreseeable risks, which are classified as minimal because they arise exclusively from the additional procedures performed for research purposes and do not include risks related to dental treatment, which would be indicated regardless of your participation in the study. The blood collection required for the laboratory tests may cause mild pain at the puncture site, slight bruising, minor bleeding, or dizziness. To reduce these risks, blood collection will be performed by a trained professional familiar with biosafety standards. There is also a rare risk of changes in blood test results resulting from the medications used in the study; this will be monitored through laboratory tests during the research. The researchers responsible will inform you of your test results in person during the clinical follow-up visits planned for the study or, when necessary, by telephone, as soon as the laboratory results are released. If any abnormality is identified, you will be examined and receive appropriate guidance and may be referred for medical care, if necessary. In addition, there is a minimal risk of a breach of the confidentiality of your personal and health information. To minimize this risk, all information collected will be coded and securely stored, as described at the end of this form.

This study may provide potential direct benefits through the clinical and laboratory monitoring performed during the research, including blood tests before and after the surgical procedures, contributing to the early identification of possible hematological, hepatic, or renal changes. You will be informed of your test results as soon as the analyses have been completed and, if clinically relevant abnormalities are identified, you will receive guidance and be referred for specialized medical care, when necessary. Furthermore, the study results may expand scientific knowledge about the hematological safety of dipyrone in the dental setting, particularly in comparison with paracetamol, providing relevant evidence to support clinical decision-making. Thus, in the medium and long term, the findings may benefit healthcare professionals and patients undergoing dental surgery by contributing to the safer and more rational use of analgesics in the dental postoperative period.

You will not incur any costs or receive any financial benefit for participating in this study. The study medications and laboratory tests related to the research will be provided by the researchers at no cost to you. If travel is necessary for the planned blood collections, your transportation expenses will be reimbursed by the researchers. The materials used for the tooth extractions will be provided by the Oral and Maxillofacial Surgery Clinic of the UFJF School of Dentistry, as they are part of the institution's routine care. Nevertheless, if you suffer any harm as a result of the activities performed with you in this study, you have the right to seek compensation. You will be given all the information you wish to receive about this study, and you are free to participate or refuse to participate. Even if you agree to participate now,

you may change your mind or withdraw from the study at any time. Your participation is voluntary, and choosing not to participate will not result in any disadvantage, penalty, or change in the care you receive. The researcher will not disclose your name. The study results will be made available to you once the study has been completed. Your name or any material that identifies you as a participant will not be disclosed without your permission. You will not be identified in any publication resulting from this research.

This consent form is printed in two original copies: one will be kept by the researcher responsible, and the other will be given to you. Your personal data and health information will be collected during the clinical, surgical, and laboratory stages of this study and will be coded to ensure de-identification. When necessary, clinical, radiographic, and dental information from your medical/dental record may also be used, but only after you have signed this consent form. The processing and analysis of the information will be carried out exclusively by the researchers responsible for scientific purposes related to this study, in accordance with the Brazilian General Data Protection Law (Law No. 13,709/2018 – LGPD) and Resolution No. 466/12 of the National Health Council. The data will be stored securely, in password-protected digital files and physical documents kept in a secure institutional environment, with access restricted to the research team, for a minimum period of 5 years after the end of the study. The data may be shared exclusively among authorized members of the research team, when necessary for the conduct of this research, while remaining coded and protected by access controls to ensure confidentiality, integrity, and security, in accordance with the guidelines of Official Circular Letter No. 02/2021/CONEP. After this minimum 5-year storage period, the data may be deleted, anonymized, or retained, when applicable, for as long as necessary to comply with legal or regulatory obligations or to exercise rights, as provided for in Articles 15 and 16 of Law No. 13,709/2018 (LGPD).

I declare that I agree to participate in this study and that I have been given the opportunity to read this form and have my questions answered.

Juiz de Fora, _____ of _____of 20

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Participant's signature Researcher's signature

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