DATE: JANUARY 1,2024
INFORMED CONSENT FORM
NAME OF THE STUDY:
Effect of Single Dose Intravenous Dexamethasone on Postoperative Pain and Complications in Jaw Surgery Under General Anesthesia

This study is a scientific research. Before deciding whether or not you want to participate in the study, it is important that you understand why the study is being conducted, how your information will be used, what the study involves, and the possible benefits and risks. Please take the time to read the following information carefully.

WHAT IS THE PURPOSE OF THE STUDY? In this study, we aimed to observe the effects of intravenous (IV) dexamethasone, which is routinely administered during surgery to patients undergoing surgery for jaw cysts and impacted tooth extractions under general anesthesia at the Faculty of Dentistry, on postoperative pain and other possible complications (facial edema, limited mouth opening). WHAT ARE THE TREATMENTS/PROCEDURES TO BE APPLIED IN THE STUDY? (WHAT IS THE METHOD OF THE STUDY?

In our study, no additional treatment or procedure will be applied to you except for your surgery and postoperative control examinations. You will be given general anesthesia for your surgery to be performed. After you wake up from general anesthesia, you will be monitored in the Patient Recovery Department in our operating room under the supervision of an anesthesiologist and nurse until the effect of anesthesia has completely worn off, and you will be discharged on the same day. Before discharge, the dentists responsible for your surgery from the Oral, Dental and Maxillofacial Surgery Department will perform your control examination and create your prescription. You will be given a Home Pain Monitoring Form to fill out at home and you will be asked to bring this form to the control examination to be held the next day. We aim to evaluate your postoperative pain, medications you use and clinical examination findings and observe the effects of the drug called dexamethasone, which is routinely applied during surgery, on pain, mouth opening and facial edema.

WHAT IS THE SCOPE OF THE STUDY?

Our study includes all adult patients who will undergo cyst excision of up to half the jaw size (unilateral) in the maxilla or impacted tooth extraction under general anesthesia. There will be no experimental procedures or applications in our study.

HOW LONG IS THE DURATION OF THE STUDY?

We plan to complete our study within 1 year.

WHAT IS THE ESTIMATED NUMBER OF VOLUNTEERS EXPECTED TO PARTICIPATE IN THE STUDY? We expect 60 patient volunteers to participate in our study.

WHAT DO I NEED TO DO IN THE STUDY? If you voluntarily accept to participate in the study, you will be given a 'Home Pain Monitoring Form' when you are discharged, and you will be asked to fill out this form correctly and bring it to the control examination on Day 1. You must allow the information obtained during this process to be evaluated and you must read and sign this form.

DO I HAVE TO PARTICIPATE IN THIS STUDY?:

Whether or not you participate in the study is completely up to your free will. If you decide to participate in the study, you will be given this "Informed Consent Form" to sign. If you decide to participate, you are free to withdraw from the study at any time. This will not affect the standard of treatment you receive, and any necessary treatment will continue.

Please note that the researcher responsible for the study (Study Doctor) may decide that your continued participation in the study is not in your best interest and may remove you from the study for your own benefit.

Your withdrawal from the study will occur if you no longer meet the eligibility criteria for participation in the study or if your health is at risk in any way, if your doctor decides to stop you from participating in the study, or if the researchers are no longer able to contact you.

WHAT ARE THE POSSIBLE SIDE EFFECTS AND RISKS TO EXPECT FROM PARTICIPATION IN THE STUDY?

There are no possible side effects or risks that may arise from participating in the study.

WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATION IN THE STUDY? You will not gain any personal benefit from participating in the study. WHAT IS THE COST OF PARTICIPATION IN THE STUDY?
According to the principle that scientific studies should not be conducted with financial concerns, you do not need to make a payment to participate in this study. You will not be paid for your participation.

HOW WILL MY PERSONAL INFORMATION BE USED?

By signing this form, you will have consented to your research doctor and his staff collecting and using your personal information (Study Data) for the study. This consent you have given regarding the use of all your personal study data such as your date of birth and gender is valid indefinitely as a rule and does not have any expiration period. If you do not want your data to be used, you can always waive this consent by informing your doctor.
The researchers conducting the study, the ethics committee and the relevant health authorities can directly access your medical records when necessary.
will be kept confidential and will not be shared with the public. The results of the study may be published in medical publications, but your identity will continue to be kept confidential in these publications.

You always have the right to ask your doctor for information about your collected study data. You also have the right to request correction of any errors in this data. If you have any requests on these issues, consult your doctor.
If you withdraw your consent, your doctor will no longer be able to use your study data or share it with anyone, even if your identity is confidential.

WILL I BE INFORMED AT THE END OF THE RESEARCH?
When you request, your evaluation results will be shared with you verbally and you will be given feedback on the quantitative data obtained from the scales.
RESPONSIBLE PERSONS YOU CAN CONTACT FOR ANY QUESTIONS:
Dr. Lecturer Funda Arun 05327494542
Res. Asst. Emine Taşkın 05069674172
HOW MAY NEW INFORMATION AFFECT MY ROLE IN THE STUDY?

Any new information that emerges during the study will be communicated to you immediately. VOLUNTARY PARTICIPATION STATEMENT

I make my decision to participate in this study completely voluntarily. I am aware that I can refuse to participate in this study or that I have the right to withdraw at any time after participating without taking any responsibility. I am aware that this situation will not affect the care and treatments I will receive at the health institution. If I withdraw from the study at any time, I will evaluate my reasons for leaving, the consequences of my withdrawal, and the treatments I will receive in the following period with my doctor.

CONSENT TO PARTICIPATE IN THE STUDY

I have discussed all the above explanations in detail with my doctor and he has answered all my questions about my treatment. I have read and understood this informed consent document. I accept to participate in this study without any pressure and I sign this consent document of my own free will. I know that this approval does not invalidate any legal provisions protecting my legal rights. My doctor has given me a copy of this document to keep and a document containing the points I will pay attention to during the study.

Patient's Name Surname: Date: Signature:

If applicable

Parent/Guardian's Name Surname: Date: Signature:

Researcher's Name Surname: Date: