



**KÜTAHYA HEALTH SCIENCES UNIVERSITY CLİNICAL RESEARCH ETHİCS  
COMMITTEE APPLICATION FORM**

**STUDY NAME: ASSESSİNG THE FREQUENCY OF TRİGEMİNOCARDİAC REFLEX İN  
MAXİLLARY AND MANDİBULAR CYST OPERATİONS**

**FORM DATE: December 2022**

**NCT number: Not yet received**



**KÜTAHYA UNIVERSITY OF HEALTH SCIENCES  
RECTORATE**

**INTERVENTIONAL CLINICAL TRIALS  
TO THE CHAIRMAN OF THE ETHICS COMMITTEE**

I kindly request your information and necessity for the examination of our research titled "Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations " by your board.

**Responsible Researcher  
Assistant Professor Bedreddin Cavlı**



## KÜTAHYA HEALTH SCIENCES UNIVERSITY RECTORATE INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE RESEARCH BUDGET FORM

### A. RESEARCH INFORMATION

<b>Supportive</b>
Asst. Professor, Bedreddin Cavlı <a href="mailto:bedreddin.cavli@ksbu.edu.tr">bedreddin.cavli@ksbu.edu.tr</a> 05051590606
<b>Legal Representative</b>
Bedreddin Cavlı <a href="mailto:bedreddin.cavli@ksbu.edu.tr">bedreddin.cavli@ksbu.edu.tr</a> +905051590606

<b>Name of the study</b>			
Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations			
<b>Protocol number/code</b>			
<b>The number/code given to the research by the Turkish Medicines and Medical Devices Agency (TİTCK) and the Ethics Committee (EK)</b>			
TİTCK		EK	

### B. RESEARCH CENTRES

<b>Please indicate the centres participating in the research from our country:</b>
1. Kütahya Health Sciences University Faculty of Dentistry, Department of Oral, Dental and Maxillofacial Surgery

## C. SERVICE PROCUREMENT

### *Services to be received from Turkey*

<b>1. Specify the services to be received from the research centre and their number</b>	
<b>Process Name</b>	<b>Number of transactions for one volunteer</b>
Monitoring of patients	1

### **2. Specify the services to be received from outside the research centres and their number**

<b>Process Name</b>	<b>Number of transactions for one volunteer</b>
-	-

### *Services to be received from outside Turkey*

<b>3. Specify the services to be received from outside Turkey and their number</b>	
<b>Process Name</b>	<b>Number of transactions for one volunteer</b>
-	-

## D. PAYMENTS

*Please indicate the amounts stated in this section in Turkish Lira.*

<b>1. Please indicate the amount to be paid to the research centre, excluding researcher payments, for each subject who completes the study:</b>	
<b>Centre Name</b>	<b>Amount (for 1 volunteer)</b>
-	0 TL

<b>2. State the amount to be paid to the research centre on behalf of the researcher for each volunteer who completes the study:</b>	
<b>Centre Name</b>	<b>Amount (for 1 volunteer)</b>
-	0 TL

**3. If volunteers will be paid, explain in detail and indicate the maximum amount of payment planned to be paid to a volunteer during the study:**

Volunteer patients will not receive any payment.

**4. Indicate other payments, if any, and the amount:**

Process name	Amount
-	-

**E. BUDGET SOURCE**

The researcher himself	<input checked="" type="checkbox"/>
Finance organisation/institution	<input type="checkbox"/>
Description:	

**F. SUPPORTER'S DECLARATION (SIGNATURE)**

Please indicate the total* budget allocated for the research in Turkey (in Turkish Lira)	340 TL
The budget was calculated considering the transaction costs dated. It is not the total amount allocated for one volunteer, but the total amount including investigator payments, centre payments and operational expenses allocated for our country during the whole research.	

**Work with this budget form;**

- The information stated in the form is correct,
- I undertake that the payments related to the research protocol, other concurrent treatment and research-induced rescue treatment costs foreseen to be made during the research specified in the research protocol will not be paid to the volunteer and the Social Security Institution, and will be paid by the sponsor (person or organisation).

Handwritten name and surname		
Telephone number		
Email address		
Date (in days/months/years)		
Signature		



## **KÜTAHYA HEALTH SCIENCES UNIVERSITY RECTORATE INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE RESEARCH PROTOCOL FORM**

**Title of the study:** Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations.

**Title, name, field of specialization and place of duty of the principal investigator:**

Asst. Professor Bedreddin Cavlı

Oral and Maxillofacial Surgery- Kütahya Health Sciences University Faculty of Dentistry

**Title, names, fields of specialization and duty stations of all researchers who will be involved in the study:**

Responsible Researcher: Asst. Professor, Bedreddin Cavlı

Oral and Maxillofacial Surgery- Kütahya Health Sciences University Faculty of Dentistry

Assistant Researcher: Research Assistant, Şeyma Kale

Oral and Maxillofacial Surgery- Kütahya Health Sciences University Faculty of Dentistry

Counsellors:

Asst. Professor Necmiye Şengel

Anesthesiology and Reanimation- Gazi University Faculty of Dentistry

Professor Ziver Ergun Yücel

Oral and Maxillofacial Surgery- Gazi University Faculty of Dentistry

**Place of the study:** Kütahya Health Sciences University Faculty of Dentistry, Department of Oral, Dental and Maxillofacial Surger

<b>PHASE AND TYPE OF RESEARCH</b>	Phase 1	<input type="checkbox"/>
	Phase 2	<input type="checkbox"/>
	Phase 3	<input type="checkbox"/>
	Phase 4	<input type="checkbox"/>
	Observational drug study	<input type="checkbox"/>
	Medical device clinical research	<input type="checkbox"/>
	Performance evaluation studies conducted with in vitro medical diagnostic devices	<input type="checkbox"/>

	Non-drug clinical research	<input checked="" type="checkbox"/>
Please specify if other:		

### Research hypothesis:

**$\mu \neq 0$  hypothesis:** The location of the cyst in the maxilla or mandible does not affect the prevalence of reflex during the enucleation of cystic structures.

**$\mu = 0$  hypothesis:** The location of the cyst in the maxilla or mandible influences the prevalence of reflex during the enucleation of cystic structures..

### Introduction-Purpose Section

The trigeminocardiac reflex (TCR) has entered the scientific literature as an oculocardiac reflex with strabismus surgeries (1). In cases where the V1 branch of the trigeminal nerve forms the afferent pathway of the V1 branch of the trigeminal nerve, a clinical phenomenon with vagal stimulation findings has been encountered. Since the publication of TCR in ophthalmological surgery in 1908, it has become a well-known clinical picture for ophthalmologists and anesthetists (2). The anesthetist's mastery and experience in this picture, which is met by manipulation of the ocular muscles, is of great importance. Recognition that the picture is a brainstem reflex involving the vagal pathway is critical in mastering the clinical situation. In the literature, it has been reported that V2 and V3 branches of the trigeminal nerve can also produce the reflex picture and the reflex can be seen under local anaesthesia. (3,4). Reflex is diagnosed under local anaesthesia as well as under general anaesthesia with hemodynamic data (blood pressure, heart rate) that can be monitored non-invasively.

TCR is a physiological, life-threatening response with sudden onset of severe bradycardia, hypotension and asystole with parasympathetic activation of the heart due to stimulation of the vagal nerve as a result of stimulation of any of the three branches of the trigeminal nerve. (1). It is defined as a decrease in heart rate and mean arterial blood pressure by more than 20% from baseline or a heart rate of less than 60 beats per minute due to intraoperative traction or manipulation of the trigeminal nerve. The afferent branch of the trigeminocardiac reflex arc is formed by the sensory nerve endings of the fifth cranial nerve. Neuronal signals are sent to the trigeminal sensory nucleus via the Gasserian ganglion. The sensory nucleus of the afferent reflex branch of the trigeminal nerve connects to the efferent pathway via short internuncial fibres in the reticular formation with the more distant motor nucleus of the vagus nerve. Cardioinhibitory efferent fibres originate from the motor nucleus of the vagus nerve. It transmits vagus-mediated negative chronotropic and inotropic responses to the heart and terminates in the myocardium (5).

In the maxillofacial surgery literature, there are case reports reporting the development of trigeminocardiac reflex in orthognathic surgery, dental implant surgery and maxillofacial trauma surgery and prevalence studies for major surgeries (6,7,8). Hemodynamic changes and neurological-based emergencies (e.g. vasovagal syncope) are quite common in routine oral surgical procedures performed under local anesthesia (9). Our aim was to investigate the trigeminocardiac reflex in oral surgical procedures routinely performed under local anesthesia. For this purpose, we prefer surgery of maxillary and mandibular cysts primarily among oral surgeries because of the inclusion of large tissues in the surgical field, the proximity of the cysts to the surrounding vital units (inferior alveolar nerve, nasal floor, maxillary sinus floor) and our clinical experience. There are no studies in the

literature evaluating the development of the trigeminocardiac reflex during surgical treatment of maxillary and mandibular cystic lesions.

The study will be conducted on patients referred to KSBÜ Faculty of Dentistry, Department of Oral, Dental and Maxillofacial Surgery from Oral, Dental and Maxillofacial Radiology who have maxillary or mandibular intraosseous cystic lesion with a diameter of at least 1 cm, who accept the treatment of this lesion in KSBÜ Faculty of Dentistry, Department of Oral, Dental and Maxillofacial Surgery and agree to participate in the study.

Surgical treatment of cystic lesions will be performed under local anesthesia. Heart rate, systolic and diastolic blood pressure, oxygen saturation will be monitored and evaluated during the cyst enucleation procedure. Records will be made before the start of the surgical procedure, during the administration of local anesthesia, incision, removal of the bone barrier to reach the cystic lesion and manipulation of the nerve in the enucleation of lesions associated with the nervus alveolaris inferior. Sudden changes will be recorded as they develop with continuous follow-up for the relevant phase.

In our study, trigeminocardiac reflex findings included the following criteria in parallel with the literature; a sudden decrease of 20% in heart rate or a decrease in heart rate below 60 per minute (1,10).

In our study, we will compare the related afferent nerve branches (trigeminal nerve V2/V3) in terms of the risk of trigeminocardiac reflex development.

Parameters to be evaluated:

1. Systolic blood pressure
2. Diastolic blood pressure
3. Oxygen saturation
4. Heart rate

The anxiety level of the patients will be assessed with the Amsterdam Preoperative Anxiety and Information Score Scale (APAIS) and State-Trait Anxiety Inventory (STAI-S) in order to differentiate TKR from common neurological emergencies (e.g. vasovagal syncope) due to dental phobia. State Anxiety Scale was developed in 1970 and its Turkish form was adapted in 1983 and validity and reliability study was conducted. APAIS was translated into Turkish for the first time in our country in 2007 and it was found that APAIS and STAI-S were correlated with each other in the studies conducted(11).

#### Amsterdam Preoperative Anxiety and Information Scale (APAIS)

	Not all 1	2	3	4	Very much 5
I am worried about about anesthetics					
The anesthetics is on my mind continually					
I would like to know as much as possible about the anesthetic					
I am worried about the procedure.					
The procedure is on my mind continually.					
I would like to know as much as possible about the procedure					

STAI-S ( The State-Trait Anxiety Inventory)

		Not at all	A littl e	So me wha t	Very Much So
1.	I feel calm	(1)	(2)	(3)	(4)
2.	I feel secure	(1)	(2)	(3)	(4)
3.	I feel tense	(1)	(2)	(3)	(4)
4.	I feel strained	(1)	(2)	(3)	(4)
5.	I feel at ease	(1)	(2)	(3)	(4)
6.	I feel upset	(1)	(2)	(3)	(4)
7.	I am presently worrying over possible misfortunes	(1)	(2)	(3)	(4)
8.	. I feel satisfied	(1)	(2)	(3)	(4)
9.	I feel frightened	(1)	(2)	(3)	(4)
10.	I feel uncomfortable	(1)	(2)	(3)	(4)
11.	I feel self confident	(1)	(2)	(3)	(4)
12.	I feel nervous	(1)	(2)	(3)	(4)
13.	I feel jittery	(1)	(2)	(3)	(4)
14.	I feel indecisive	(1)	(2)	(3)	(4)
15.	I am relaxed	(1)	(2)	(3)	(4)
16.	I feel content.	(1)	(2)	(3)	(4)
17.	I am worried	(1)	(2)	(3)	(4)
18.	I feel confused	(1)	(2)	(3)	(4)
19.	I feel steady	(1)	(2)	(3)	(4)
20.	I feel pleasant.	(1)	(2)	(3)	(4)

**Inclusion criteria:**

Adults aged 18 years and over

Patients with cystic lesions at least 1 cm in diameter in the maxilla or mandible

Individuals without any systemic disease

**Exclusion criteria:**

Female subjects who are pregnant or breastfeeding

Presence of systemic disease

Presence of mental or neurological illness

Antidepressant use

### **Sample selection and statistical method to be used:**

Last year, it was determined that the number of patients who applied to the Department of Oral and Maxillofacial Surgery for the treatment of intraosseous lesions was around n=60. With the simple random sampling method, it was seen that 33 patients could represent the universe with 5% error and 95% confidence level. It was seen that at least 33 patients should be included in the study. In the study of Bohluli (2010), which is the reference article, n=23 patients included in the study, 95% power and effect size level was 0.48. In summary, it is seen that the study has sufficient power and the effect size level is quite sufficient. It was planned to include 34 patients in the study in order to divide the research arms into balanced groups.

Regarding the analysis of data; descriptive statistics will be presented with mean, standard deviation values. In order to examine whether the measurements in the study are different according to the characteristics of the study groups, Mann Whitney U test and Kruskall Wallis test analyses are considered. Friedman and Wilcoxon sign test will be used in the evaluation of measurements to be made at different times. Spearman correlation analysis will be applied to examine the relationships between measurement values. Chi-Square analysis will be performed for proportional evaluations of the groups. In the study, p values less than 0.05 will be considered significant. Analyses will be analyses with SPSS 25.0 . The power level and effect size calculations calculated in the study were determined with G\*Power Version 3.1.7.

### **List of References**

1. Schaller, B., Probst, R., Strelbel, S., & Gratzl, O. (1999). Trigeminocardiac reflex during surgery in the cerebellopontine angle. *Journal of neurosurgery*, 90(2), 215-220.
2. Aschner, B. (1908). Ueber einen Bisher noch nicht Beschriebenen Reflex vom Auge auf Kreislauf und Atmung: Verschwinden des Radialispulses bei Druck auf das. *Review of Oculocardiac Reflex When Facial Surgery*.
3. James, I., Huang, S., Yu, H. C., & Chang, Y. C. (2017). Occurrence of trigeminocardiac reflex during dental implant surgery: an observational prospective study. *Journal of the Formosan Medical Association*, 116(10), 742-747.
4. James, I., Huang, S., Chang, H. H., Lin, C. P., Liao, W. C., Kao, C. T., & Huang, T. H. (2018). Trigeminocardiac reflex during non-surgical root canal treatment of teeth with irreversible pulpitis. *Journal of the Formosan Medical Association*, 117(6), 512-517.
5. Meuwly, C., Golanov, E., Chowdhury, T., Erne, P., & Schaller, B. (2015). Trigeminal cardiac reflex: new thinking model about the definition based on a literature review. *Medicine*, 94(5).
6. Bohluli, B., Bayat, M., Sarkarat, F., Moradi, B., Tabrizi, M. H. S., & Sadr-Eshkevari, P. (2010). Trigeminocardiac reflex during Le Fort I osteotomy: a case-crossover study. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology*, 110(2), 178-181.

7. Mhamunkar, P. A., Kolari, V., & Sequeira, J. (2022). Evaluation of Trigeminocardiac Reflex in Patients Undergoing Elevation of Zygomatic Fractures. *Cureus*, 14(2).
8. Elsayed, S. A. H., Hegab, A. F., & Alkatsh, S. S. Y. (2019). Does surgical release of TMJ bony ankylosis increase the risk of trigeminocardiac reflex? A retrospective cohort study. *Journal of Oral and Maxillofacial Surgery*, 77(2), 391-397.
9. Edmondson, H. D., Gordon, P. H., Lloyd, J. M., Meeson, J. E., & Whitehead, F. I. H. (1978). Vasovagal episodes in the dental surgery. *Journal of Dentistry*, 6(3), 189-195.
10. Schaller, B. J., Filis, A., & Buchfelder, M. (2008). Trigemino-cardiac reflex in humans initiated by peripheral stimulation during neurosurgical skull-base operations. Its first description. *Acta Neurochirurgica*, 150(7), 715-718.
11. ARLI, Ş. K. (2017). Ameliyat öncesi anksiyetenin APAIS ve STAI-I ölçekleri ile değerlendirilmesi. *Hacettepe Üniversitesi Hemşirelik Fakültesi Dergisi*, 4(3), 38-47.



## KÜTAHYA HEALTH SCIENCES UNIVERSITY RECTORATE INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE APPLICATION FORMS

1. APPLICATION PETITION	<input checked="" type="checkbox"/>
2. APPLICATION CONTENT FORM	<input checked="" type="checkbox"/>
3. APPLICATION FORM	<input checked="" type="checkbox"/>
4. CONTRACT	<input checked="" type="checkbox"/>
4. RESEARCH BUDGET	<input checked="" type="checkbox"/>
5. CVS	<input checked="" type="checkbox"/>
6. INFORMED CONSENT FORM	<input checked="" type="checkbox"/>
7. MATERIAL PURCHASE CONSENT FORM (if necessary)	<input type="checkbox"/>
8. QUESTIONNAIRE ETC. FORMS USED	<input checked="" type="checkbox"/>
9. APPROVAL CERTIFICATE OF THE RELEVANT DEPARTMENT HEAD / HEAD OF THE MAIN DISCIPLINE / LABORATORY SUPERVISORS	<input type="checkbox"/>
10. INSTITUTIONAL PERMISSION CERTIFICATE	<input checked="" type="checkbox"/>
11. CONFIRMATION WRITTEN THAT YOU ARE A STUDENT OF THE RELATED INSTITUTE (if the research is a thesis and the researcher is a student of the institute)	<input type="checkbox"/>
12. 3 PUBLICATIONS RELATED TO RESEARCH	<input checked="" type="checkbox"/>
13. DATA SECURITY AGREEMENT (For necessary researches)	<input type="checkbox"/>
14. GCP, GLP AND HELSINKI DECLARATION COMMITMENT	<input checked="" type="checkbox"/>
15. Delivery of the application file to the Ethics Committee secretariat	<input checked="" type="checkbox"/>

**Tick the relevant boxes with a cross.**

**Researches with incomplete application forms will not be evaluated.**

**I undertake that I have submitted all documents completely.**

**Title of the Study :** Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations

**Responsible Researcher:** Asst. Professor Bedreddin Cavlı

**Signature and Date :**



## KÜTAHYA HEALTH SCIENCES UNIVERSITY RECTORATE INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE CLINICAL RESEARCH APPLICATION FORM

### A. SUMMARY OF RESEARCH

<b>Supportive</b>	DDS, <u>Asst. Professor</u> , Bedreddin Cavlı <a href="mailto:bedreddin.cavli@ksbu.edu.tr">bedreddin.cavli@ksbu.edu.tr</a> 05051590606
<b>Legal representative</b>	DDS, <u>Asst. Professor</u> , Bedreddin Cavlı
<b>Title of the research</b>	Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations
<b>Protocol code</b>	
<b>Status of research</b>	National For academic purposes (Individual research project)
<b>Nature of the research</b>	Method clinical trial
<b>Phase of</b>	It is not a phase study.
<b>Investigated medical condition or disease</b>	Evaluation of the frequency of trigeminocardiac reflex development during surgical treatment of jaw cysts
<b>Research methodology</b>	During the surgical treatment of cysts in the jaws, patients will be monitored (heart rate, blood pressure, oxygen saturation) and trigeminocardiac reflex development will be monitored.
<b>Place of production</b>	Research product will not be used .
<b>Comparison product / method</b>	Research product will not be used
<b>Place of production</b>	Research product will not be used
<b>Placebo</b>	Research product will not be used
<b>Place of production</b>	Research product will not be used
<b>Arms- Interventions</b>	Cystic lesions in the maxilla and mandible will be evaluated by comparing the activity of the V2 and V3 branches of the trigeminal nerve in the development of the trigeminocardiac reflex. The code Group 1 will be used for cystic lesions in the maxilla and Group 2 will be used for cystic lesions in the mandible. There is no control group in the study.

<b>Purpose of the research</b>	<p>The trigeminocardiac reflex (TCR) has entered the scientific literature as an oculocardiac reflex with strabismus surgeries (1). In cases where the V1 branch of the trigeminal nerve forms the afferent pathway, a clinical phenomenon with vagal stimulation findings has been encountered. Since its publication in ophthalmological surgery in 1908, it has become a well-known clinical picture for ophthalmologists and anesthetists. (2). The anesthetist's mastery and experience in this picture, which is met by manipulation of the ocular muscles, is of great importance. Recognition that the picture is a brainstem reflex involving the vagal pathway is critical in mastering the clinical situation. In the literature, it has been reported that V2 and V3 branches of the trigeminal nerve can also produce the reflex picture and the reflex can be seen under local anesthesia. (3,4). Reflex is diagnosed under local anesthesia as well as under general anesthesia with hemodynamic data (blood pressure, heart rate) that can be monitored non-invasively.</p> <p>TCR is a physiological, life-threatening response with sudden onset of severe bradycardia, hypotension and asystole with parasympathetic activation of the heart due to stimulation of the vagal nerve as a result of stimulation of any of the three branches of the trigeminal nerve. (1). It is defined as a decrease in heart rate and mean arterial blood pressure by more than 20% from baseline or a heart rate of less than 60 beats per minute due to intraoperative traction or manipulation of the trigeminal nerve. The patients are normotensive or hypotensive (5). The afferent branch of the trigeminocardiac reflex arc is formed by the sensory nerve endings of the fifth cranial nerve. Neuronal signals are sent to the trigeminal sensory nucleus via the Gasserian ganglion. The sensory nucleus of the afferent reflex branch of the trigeminal nerve connects to the efferent pathway via short internuncial fibres in the reticular formation with the more distant motor nucleus of the vagus nerve. Cardioinhibitory efferent fibres originate from the motor nucleus of the vagus nerve. It transmits vagus-mediated negative chronotropic and inotropic responses to the heart and terminates in the myocardium.</p> <p>In the maxillofacial surgery literature, there are case reports reporting the development of trigeminocardiac reflex in orthognathic surgery, dental implant surgery and maxillofacial trauma surgery and prevalence studies for major surgeries. (6,7,8). Hemodynamic changes and neurological-based emergencies (e.g. vasovagal syncope) are quite common in routine oral surgical procedures performed under local anesthesia (9). Our aim was to investigate the trigeminocardiac reflex in oral surgical procedures routinely performed under local anesthesia. For this purpose, we prefer surgery of maxillary and mandibular cysts primarily among oral surgeries because of the inclusion of large tissues</p>
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	<p>in the surgical field, the proximity of the cysts to the surrounding vital units (inferior alveolar nerve, nasal floor, maxillary sinus floor) and our clinical experience. There are no studies in the literature evaluating the development of the trigeminocardiac reflex during surgical treatment of maxillary and mandibular cystic lesions.</p>
<p><b>Scope of the research</b></p>	<p>The study will be conducted on patients referred to KSBÜ Faculty of Dentistry, Department of Oral, Dental and Maxillofacial Surgery from Oral, Dental and Maxillofacial Radiology who have maxillary or mandibular intraosseous cystic lesion with a diameter of at least 1 cm, who accept the treatment of this lesion in KSBÜ Faculty of Dentistry, Department of Oral, Dental and Maxillofacial Surgery and agree to participate in the study.</p> <p>Surgical treatment of cystic lesions will be performed under local anesthesia. Heart rate, systolic and diastolic blood pressure, oxygen saturation will be monitored and evaluated during the cyst enucleation procedure. Records will be made before the start of the surgical procedure, during the administration of local anesthesia, incision, removal of the bone barrier to reach the cystic lesion and manipulation of the nerve in the enucleation of lesions associated with the nervus alvelolaris inferior. Sudden changes will be recorded as they develop with continuous follow-up for the relevant phase.</p> <p>In our study, trigeminocardiac reflex findings included the following criteria in parallel with the literature; a sudden decrease of 20% in heart rate or a decrease in heart rate below 60 per minute (1,10). In our study, we will compare the related afferent nerve branches (trigeminal nerve V2/V3) in terms of the risk of trigeminocardiac reflex development.</p> <p>Parameters to be evaluated:</p> <ol style="list-style-type: none"> <li>1. Systolic blood pressure</li> <li>2. Diastolic blood pressure</li> <li>3. Oxygen saturation</li> <li>4. Heart rate</li> </ol> <p>The anxiety level of the patients will be assessed with the Amsterdam Preoperative Anxiety and Information Score Scale (APAIS) and State-Trait Anxiety Inventory (STAI-S) in order to differentiate TKR from common neurological emergencies (e.g. vasovagal syncope) due to dental phobia. State Anxiety Scale was developed in 1970 and its Turkish form was adapted in 1983 and validity and reliability study was conducted. APAIS was translated into Turkish for the first time in our country in 2007 and it was found that APAIS and STAI-S were correlated with each other in the studies conducted (11).</p>

	<p>1. Schaller, B., Probst, R., Strelbel, S., &amp; Gratzl, O. (1999). Trigeminocardiac reflex during surgery in the cerebellopontine angle. <i>Journal of neurosurgery</i>, 90(2), 215-220.</p> <p>2. Aschner, B. (1908). Ueber einen Bisher noch nicht Beschriebenen Reflex vom Auge auf Kreislauf und Atmung: Verschwinden des Radialispulses bei Druck auf das. <i>Review of Oculocardiac Reflex When Facial Surgery</i>.</p> <p>3. James, I., Huang, S., Yu, H. C., &amp; Chang, Y. C. (2017). Occurrence of trigeminocardiac reflex during dental implant surgery: an observational prospective study. <i>Journal of the Formosan Medical Association</i>, 116(10), 742-747.</p> <p>4. James, I., Huang, S., Chang, H. H., Lin, C. P., Liao, W. C., Kao, C. T., &amp; Huang, T. H. (2018). Trigeminocardiac reflex during non-surgical root canal treatment of teeth with irreversible pulpitis. <i>Journal of the Formosan Medical Association</i>, 117(6), 512-517.</p> <p>5. Meuwly, C., Golanov, E., Chowdhury, T., Erne, P., &amp; Schaller, B. (2015). Trigeminal cardiac reflex: new thinking model about the definition based on a literature review. <i>Medicine</i>, 94(5).</p> <p>6. Bohluli, B., Bayat, M., Sarkarat, F., Moradi, B., Tabrizi, M. H. S., &amp; Sadr-Eshkevari, P. (2010). Trigeminocardiac reflex during Le Fort I osteotomy: a case-crossover study. <i>Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontology</i>, 110(2), 178-181.</p> <p>7. Mhamunkar, P. A., Kolari, V., &amp; Sequeira, J. (2022). Evaluation of Trigeminocardiac Reflex in Patients Undergoing Elevation of Zygomatic Fractures. <i>Cureus</i>, 14(2).</p> <p>8. Elsayed, S. A. H., Hegab, A. F., &amp; Alkatsh, S. S. Y. (2019). Does surgical release of TMJ bony ankylosis increase the risk of trigeminocardiac reflex? A retrospective cohort study. <i>Journal of Oral and Maxillofacial Surgery</i>, 77(2), 391-397.</p> <p>9. Edmondson, H. D., Gordon, P. H., Lloyd, J. M., Meeson, J. E., &amp; Whitehead, F. I. H. (1978). Vasovagal episodes in the dental surgery. <i>Journal of Dentistry</i>, 6(3), 189-195.</p> <p>10. Schaller, B. J., Filis, A., &amp; Buchfelder, M. (2008). Trigemino-cardiac reflex in humans initiated by peripheral stimulation during neurosurgical skull-base operations. Its first description. <i>Acta Neurochirurgica</i>, 150(7), 715-718.</p> <p>11. ARLI, Ş. K. (2017). Ameliyat öncesi anksiyetenin APAIS ve STAI-I ölçekleri ile değerlendirilmesi. <i>Hacettepe Üniversitesi Hemşirelik Fakültesi Dergisi</i>, 4(3), 38-47.</p>
<b>Design of the research</b>	Cross-sectional, prospective cohort
<b>Volunteer group</b>	<ul style="list-style-type: none"> <li>- Healthy volunteers</li> <li>- Male</li> <li>- Women</li> </ul>

	<ul style="list-style-type: none"> <li>- Adults</li> </ul>	
<b>Volunteer age range</b>	Patients aged 18 years and older	
<b>Volunteers</b>	Total	34 adults
	Distribution	17- Patients with maxilla cyst 17- Patients with mandibular cyst
<b>Inclusion criteria</b>	<p>Patients over 18 years of age</p> <p>Patients with cystic lesions up to 1 cm in diameter in the maxilla and mandible</p> <p>Patients without any systemic problems</p>	
<b>Exclusion criteria</b>	<p>Female patients who are pregnant or breastfeeding</p> <p>Patients with systemic problems</p> <p>Patients with mental or neurological disorders</p> <p>Patients taking antidepressants</p>	
<b>Duration of research</b>	Total	1 year
	Volunteer Recruitment Start (Beginning of the research)	
	Volunteer Recruitment End	
<b>End point</b>	The study will be finalised after data from 34 patients are obtained.	
<b>Evaluation of results</b> <i>(Outcome/Endpoint)</i>	<p>Heart rate, systolic and diastolic blood pressure, oxygen saturation will be monitored during the cyst enucleation procedure (Contec Medical Systems, Hebei, China). Records during the process will be taken in 5 stages: before starting the surgical procedure, application of local anesthesia, incision, removal of the bone barrier to reach the cystic lesion, manipulation of the cystic lesion. Sudden changes that occur during the process will be recorded together with the process in which they occur.</p> <p>(E.g. during local anesthesia)</p> <p>Initial heart rate: 80 beats/min</p> <p>End of procedure heart rate: 78 beats/min</p> <p>Sudden presence of bradycardia or tachycardia during the procedure;</p> <p>Sudden change in heart rate: 80&gt;58 or 80&gt;98)</p> <p>Patients will be asked to complete the Situational Anxiety Inventory (STAI-S) and the Amsterdam Preoperative Anxiety and Information Scale (APAIS) forms before the procedure in order to evaluate the relationship between hemodynamic changes that may occur and anxiety.</p>	
<b>Statistical Analysis</b>	Last year, it was determined that the number of patients who applied to the Department of Oral and Maxillofacial Surgery for the treatment of intraosseous lesions was around n=60. With the simple random sampling method, it was seen that 33 patients could represent the universe with 5% error	

	<p>and 95% confidence level. It was seen that at least 33 patients should be included in the study. In the study of Bohluli (2010), which is the reference article, n=23 patients included in the study, 95% power and effect size level was 0.48. In summary, it is seen that the study has sufficient power and the effect size level is quite sufficient. It was planned to include 34 patients in the study in order to divide the research arms into balanced groups.</p> <p>Regarding the analysis of data; descriptive statistics will be presented with mean, standard deviation values. In order to examine whether the measurements in the study are different according to the characteristics of the study groups, Mann Whitney U test and Kruskall Wallis test analyses are considered. Friedman and Wilcoxon sign test will be used in the evaluation of measurements to be made at different times. Spearman correlation analysis will be applied to examine the relationships between measurement values. Chi-Square analysis will be performed for proportional evaluations of the groups. In the study, p values less than 0.05 will be considered significant. Analyses will be analyses with SPSS 25.0. The power level and effect size calculations calculated in the study were determined with G*Power Version 3.1.7.</p>
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<b>Coordinator</b>	Coordinating centre	Kütahya Health Sciences University Faculty of Dentistry Department of Oral, Dental and Maxillofacial Surgery Kütahya Health Sciences University Faculty of Dentistry Department of Oral, Dental and Maxillofacial Surgery
	Coordinator (principal investigator in single-centre studies)	Bedreddin Cavlı
	Contact	05051590606 bedreddin.cavli@ksbu.edu.tr
<b>Administrative Responsible (if applicable)</b>	Name and surname	-
	Place of assignment	-
	Contact	-

#### Research centers

	Research centres	Principal Investigator (Area of Expertise) (Telephone)
1	Kütahya Health Sciences University Faculty of Dentistry Oral, Dental and Maxillofacial Surgery	Bedreddin Cavlı 05051590606

#### Information for bioavailability/bioequivalence studies

<b>Licence status</b>	Not a bioavailability/bioequivalence study.
<b>Analytical centre/department</b>	Not a bioavailability/bioequivalence study.

<b>Tested research product</b>	Not a bioavailability/bioequivalence study.
<b>Reference product</b>	Not a bioavailability/bioequivalence study.
<b>Study design</b>	Not a bioavailability/bioequivalence study.
<b>Working periods</b>	Not a bioavailability/bioequivalence study.
<b>Previous studies</b>	Not a bioavailability/bioequivalence study.
<b>Properties of active substance</b>	
<b>Resolution</b>	No active substance will be used.
<b>Bioavailability</b>	No active substance will be used.
<b>AUC</b>	No active substance will be used.
<b>C<sub>max</sub></b>	No active substance will be used.
<b>t<sub>max</sub></b>	No active substance will be used.
<b>Elimination Half Life (t<sub>1/2</sub>)</b>	No active substance will be used.
<b>Volume of Dispersion</b>	No active substance will be used.
<b>Binding to Proteins</b>	No active substance will be used.
<b>Food Effect</b>	No active substance will be used.
<b>Metabolism and Metabolites</b>	No active substance will be used.
<b>Breakthrough</b>	No active substance will be used.
<b>Accumulation</b>	No active substance will be used.
<b>Blood collection times</b>	No active substance will be used.
<b>Substance covered by biosafety</b>	No active substance will be used.
<b>Intra-individual variability constant of the active substance (%CV)</b>	No active substance will be used.
<b>Substance to be analysed</b>	No active substance will be used.

## B. OTHER INFORMATION

### **Risk / Benefit evaluation**

There are no risk factors related to the study.

If the study is completed, it will provide important data on the frequency of trigeminocardiac reflex development, a serious clinical condition, in maxillofacial surgical procedures performed under local anaesthesia. At the same time, the effect of whether the lesion is located in the maxilla or mandible on reflex development will be evaluated. To our knowledge, there is no study on this subject in the literature and this study will provide important information to the literature for the development of trigeminocardiac reflex.

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### **Sensitive population/Vulnerable Group (*Vulnerable subjects*)**

*No sensitive population/vulnerable groups.*

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### **Privacy**

In the study, the age and gender of the patients, the jaw in which the cystic lesion is located, and the systolic and diastolic blood pressure, heart rate, oxygen saturation and changes in them during the procedure will be noted. Only the research team will have access to the documents.

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### **Payment to volunteers**

Volunteers will not receive any payment.

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### **Volunteer services**

Volunteers will not receive any payment.

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**Research / volunteer documents (*additional documentation and recruitment procedure*)**

In the study, patient cards will be created in which we will note the age, gender of the patients, in which jaw the cystic lesion is located and the changes in systolic-diastolic blood pressure, heart rate, oxygen saturation and their changes during the procedure.

In addition, STAI-T (Situational Anxiety Test) and APAIS (Amsterdam Preoperative Anxiety and Information Form) will be used to evaluate stress-anxiety and trigeminocardiac reflex development.

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**Independent data monitoring committee**

There is no independent data monitoring committee in the study.

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**Sub-study**

There is no sub-study in the research.

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**Biological material management**

Biological material will not be transferred.

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**Facility / laboratory**

No central technical facilities or laboratories will be used in the study

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**Delegation of tasks**

There are no delegated duties.

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**Referral to other health authorities**

There is no other country where research has been approved.

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**Research-specific information**

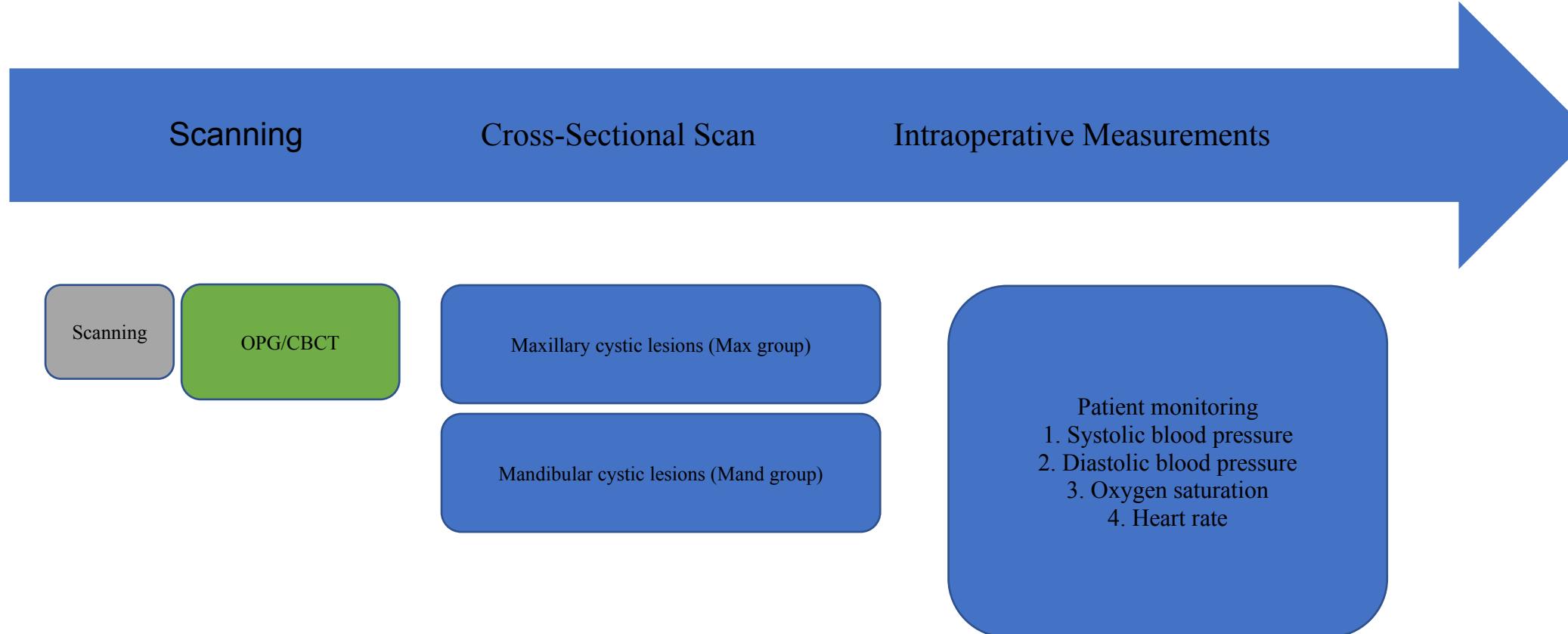
The trigeminocardiac reflex has been overshadowed by other vasovagal reflexes and is a well-defined clinical picture in ophthalmology. We believe that it should attract more attention in oral surgery where procedures are usually performed under local anaesthesia.

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**C. RESEARCH TEAM LIST**

<b>Centre Name</b>	Kütahya Health Sciences University Faculty of Dentistry Oral, Dental and Maxillofacial Surgery			
<b>Address</b>	İstiklal Neighbourhood Lala Hüseyin Paşa Street No:271 43100 KÜTAHYA			
<b>Mission</b>	<b>Name Surname</b>	<b>Title</b>	<b>Education</b>	<b>İKU Training (present/absent))</b>
<b>Principal Investigator</b>	Bedreddin Cavlı	<a href="#">Asst. Professor</a>	Dentistry-Mouth, Dental and Maxillofacial Surgery	None
<b>Assistant Researcher</b>	Şeyma Kale	Resarch Asistant	Dentistry- Dental and Maxillofacial Surgery	None
<b>Counsellor</b>	Necmiye Şengel	<a href="#">Asst. Professor</a>	Anaesthesiology and Reanimation	None
<b>Counsellor</b>	Ziver Ergun Yücel	Professor	Dentistry-Mouth, Dental and Maxillofacial Surgery	None

#### D. RESEARCH DESIGN DIAGRAM



#### E. ASSESSMENT CHART (Schedule of Assessments)

Evaluation	Scanning	Operation
Informed Voluntary Consent Form		X
Demographic information	X	
Medical history/ General physical examination	X	
Clinical data		X
CBCT	X	
Inclusion/exclusion criteria	X	
Intra-op data		X

## F. ETHICS COMMITTEE INFORMATION

<input checked="" type="checkbox"/>	<b>There is a previous rejection decision by the ethics committee of the research</b>
	-
Name of the ethics committee	Kütahya Health Sciences University Non-Interventional Clinical Research Ethics Committee
Date of decision	
Decision no.	

*This section must be filled in when applying to the Turkish Medicines and Medical Devices Agency.*

<input type="checkbox"/>	<b>Ethics committee application was made for approval of the research</b>
Name of the ethics committee	-
Application date	-
<input type="checkbox"/>	<b>There is ethics committee approval for the research.</b>
Name of the ethics committee	-
Date of decision	-
Decision no.	-

## G. RELATED DOCUMENTS

1. Research protocol
2. Protocol signature page (signed by the coordinator in multicentre studies and the principal investigator in single-centre studies)
3. Informed consent form
4. Research brochure
5. Case report form
6. Insurance documents  
(insurance certificate, insurance policy, insurance endorsements, general and special conditions of the policy)
7. Research budget form
8. CVs  
(of the principal investigators)
9. Authorisation documents (if valid)  
(with Turkish translations certified by a notary public or sworn translator)
10. Research team documents (if applicable)  
(all documents used only by the research team or used to inform the research team, such as application instructions, information texts, doctors' letters, etc.)
11. Volunteer documents (if applicable)

(patient card, patient diary, questionnaire, instructions for use, application instructions, information texts, posters, brochures, information documents explaining the intended use of the materials to be given to volunteers (electronic diary, cooler bag, etc.))

12. Ethics committee decision (original and certified copy of the original)
13. Research product file (if required)
14. GMP Certificate/Document (apostilled) (if applicable)
15. If the research is for academic purposes, a wet signed document approved by an authorised person other than the applicant stating that the research is for academic purposes  
Only for bioavailability/bioequivalence studies;
16. Certificate of supply of the investigational product and reference product(s)  
(invoice/package photocopy with serial number and expiry date)
17. Certificate of analysis of the research product

## **H. DOCUMENTS TO BE PHYSICALLY SUBMITTED**

*This section is only valid for applications to the Turkish Medicines and Medical Devices Agency.*

*All interested parties who are users of the Electronic Application System of the Agency must make their applications through the system. Documents that do not need to be physically submitted are submitted only through the Electronic Application System. The scanned versions of the documents that need to be physically submitted are submitted through the Electronic Application System; the originals are submitted by submitting them to the document unit of the Agency.*

*For applications made by real persons who are not users of the Electronic Application System of the Institution, all documents must be submitted physically.*

The following documents should be submitted physically with wet signatures or preferably with electronic signatures.

### 1. Ethics committee decision

It is essential to submit the following documents with electronic signatures through the electronic application system. However, if these documents cannot be submitted with electronic signatures, their wet signed versions can be physically submitted.

1. Research budget form
2. Insurance documents
3. Authorisation certificate
4. CV
5. Protocol signature page
6. Proof that the research is for academic purposes
7. GMP certificate/document (apostilled) 1

## **I. SIGNATURE OF THE APPLICANT**

- All documents attached to the application file are identical to the original,
- The information provided in the application is correct,
- The research will be conducted in accordance with the protocol, relevant legislation, the current Helsinki Declaration and the principles of good clinical practice,

- The investigational product (including placebo) is manufactured in accordance with GMP rules,
- The Turkish label sample of the investigational product (including placebo) was prepared in accordance with GMP guidelines,
- That the research team (including laboratory team, research nurse, research pharmacist, etc.) is informed about the research,
- That the proposed clinical trial is feasible,
- The research application is not made to more than one of the ethics committees established within the scope of the relevant Regulation at the same time,
- The progress of the research will be reported at least annually (with an annual notification form),
- Reports on serious adverse events/reactions and periodic safety reports will be submitted in accordance with the periods specified in the legislation,
- That the research is recorded in a public database, provided that the confidentiality of personal data is respected,
- The publication of the information and research results of the research in a public database by the Authority, provided that the confidentiality of trade secrets and personal data is respected within the conditions determined by the Authority,
- I agree and undertake to submit a copy of the summary of the final report within a maximum period of 1 (one) year after the end of the research (in all countries, if it is an international research).

Name and surname	Bedreddin Cavlı
Telephone number	05051590606
Email address	bedreddin.cavli@ksbu.edu.tr
Date (in days/months/years)	
Signature	



## KÜTAHYA HEALTH SCIENCES UNIVERSITY RECTORATE INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE RESEARCHERS CV FORM

### A. PERSONAL INFORMATION

Name Surname	Bedreddin Cavlı
Academic title/position	Asst. Professor
Place of assignment	Kütahya Health Sciences University Faculty of Dentistry Department of Oral and Maxillofacial Surgery
Telephone number	05051590606
Email address	bedreddin.cavli@ksbu.edu.tr

### B. EDUCATION INFORMATION

Year	Section	Institution	Degree
2015	Faculty of Dentistry	Selcuk University	-
2020	Department of Oral and Maxillofacial Surgery	Gazi University	-

### C. INFORMATION ON WORK EXPERIENCE

Date Range	Institution	Mission
2021-...	Kütahya University of Health Sciences / Department of Oral and Maxillofacial Surgery	Asst. Professor
2021	Eskisehir Oral and Dental Health Hospital	Specialist Dentist
2016-2020	Gazi University / Department of Oral and Maxillofacial Surgery	Research Asst.

### D. GENERAL INFORMATION ABOUT CLINICAL RESEARCH

#### 4. Training/certificate information on Good Clinical Practices (GCP) and clinical research:

If there is a certificate regarding the training you have received, please attach a copy.

Name and place of training/certificate	Date
-	-

**5. Clinical research information:**

**Responsible Investigator, Co-Investigator, Co-ordinator, Field Officer, Monitor, Pharmacist, etc. should be specified.**

**Write the information in this section in date order.**

Clinical research	Date Range	Mission
-	-	-

**E. SIGNATURE OF THE CV OWNER**

I accept and declare that the information I have declared above is correct and up-to-date and that I will comply with the provisions of the relevant legislation and good clinical practices regarding the conduct of clinical trials.

Name Surname	Bedreddin CAVLI
Date (in days/months/years)	
Signature	

**A. PERSONAL INFORMATION**

Name Surname	Şeyma Kale
Academic title/position	Research Asst
Place of assignment	Kütahya Health Sciences University Faculty of Dentistry Department of Oral and Maxillofacial Surgery
Telephone number	05533618111
Email address	seyma.kale@ksbu.edu.tr

**B. EDUCATION INFORMATION**

Year	Section	Institution	Degree
2018	Faculty of Dentistry	Eskişehir Osmangazi University	

**C. INFORMATION ON WORK EXPERIENCE**

Date Range	Institution	Mission
2020-....	Kütahya University of Health Sciences / Department of Oral and Maxillofacial Surgery	Research Asst.

## D. GENERAL INFORMATION ABOUT CLINICAL RESEARCH

**1. Training/certificate information on Good Clinical Practices (GCP) and clinical research:**  
**If there is a certificate regarding the training you have received, please attach a copy:**

Name and place of training/certificate	Date	
--	-	
<b>2. Clinical research information:</b> <b>Responsible Investigator, Co-Investigator, Co-ordinator, Field Officer, Monitor, Pharmacist, etc. should be specified.</b> <b>Write the information in this section in date order..</b>		
Clinical research	Date Range	Mission
-	-	-

## E. SIGNATURE OF THE CV OWNER

I accept and declare that the information I have declared above is correct and up-to-date and that I will comply with the provisions of the relevant legislation and good clinical practices regarding the conduct of clinical trials.

Name and Surname	Şeyma KALE
Date (in days/months/years)	
Signature	

## A. PERSONAL INFORMATION

Name Surname	Necmiye Şengel
Academic title/position	Asst. Professor
Place of assignment	Anaesthesiology and Reanimation - Gazi University Faculty of Dentistry
Telephone number	0505 629 10 06
Email address	<a href="mailto:necmiyesengel@hotmail.com">necmiyesengel@hotmail.com</a>

## B. EDUCATION INFORMATION

Year	Section	Institution	Degree
2008	Faculty of Medicine	Gazi University	Licence
2013	Anaesthesiology and Reanimation	Gazi University	Expertise

## C. INFORMATION ON WORK EXPERIENCE

Date Range	Institution	Mission
2018	Gazi University Faculty of Dentistry	Asst. Professor
2008-2013	Gazi University Department of Anaesthesiology and Reanimation	Research Asst.

## D. GENERAL INFORMATION ABOUT CLINICAL RESEARCH

**1. Training/certificate information on Good Clinical Practices (GCP) and clinical research:**  
If there is a certificate regarding the training you have received, please attach a copy:

Name and place of training/certificate	Date
--	-

**2. Clinical research information:**

**Responsible Investigator, Co-Investigator, Co-ordinator, Field Officer, Monitor, Pharmacist, etc. should be specified.**

**Write the information in this section in date order..**

Clinical research	Date Range	Mission
-	-	-

## E. SIGNATURE OF THE CV OWNER

I accept and declare that the information I have declared above is correct and up-to-date and that I will comply with the provisions of the relevant legislation and good clinical practices regarding the conduct of clinical trials.

Name and Surname	Necmiye Şengel
Date (in days/months/years)	
Signature	

## A. PERSONAL INFORMATION

Name Surname	Ziver Ergun Yücel
Academic title/position	Professor
Place of assignment	Oral and Maxillofacial Surgery- Gazi University Faculty of Dentistry
Telephone number	0532 395 55 58
Email address	<a href="mailto:erguny@gazi.edu.tr">erguny@gazi.edu.tr</a>

## B. EDUCATION INFORMATION

Year	Section	Institution	Degree
1980	Faculty of Dentistry	Ankara University	
1984	Department of Oral and Maxillofacial Surgery	Gazi University	

## C. INFORMATION ON WORK EXPERIENCE

Date Range	Institution	Mission
1984	Gazi University Department of Oral and Maxillofacial Surgery	Research Asst.
1985	Gazi University Department of Oral and Maxillofacial Surgery	Asst. Profesor
1986	Department of Maxillofacial Surgery, Freie Universität Berlin	Researcher
1988	Gazi University Department of Oral and Maxillofacial Surgery	Assoc. Professor
1991-1992	Guys & St. Thomas Hospital, University of London	Researcher
1995	Gazi University Department of Oral and Maxillofacial Surgery	Profesor

## D. GENERAL INFORMATION ABOUT CLINICAL RESEARCH

**1. Training/certificate information on Good Clinical Practices (GCP) and clinical research:**  
**If there is a certificate regarding the training you have received, please attach a copy:**

Name and place of training/certificate	Date
--	-

**2. Clinical research information:**

**Responsible Investigator, Co-Investigator, Co-ordinator, Field Officer, Monitor, Pharmacist, etc. should be specified.**

**Write the information in this section in date order..**

Clinical research	Date Range	Mission
-	-	-

## E. SIGNATURE OF THE CV OWNER

I accept and declare that the information I have declared above is correct and up-to-date and that I will comply with the provisions of the relevant legislation and good clinical practices regarding the conduct of clinical trials.

Name and Surname	Ziver Ergun Yücel
Date (in days/months/years)	
Signature	



**COMMITMENT  
KÜTAHYA UNIVERSITY OF HEALTH SCIENCES  
CHAIRMAN OF THE ETHICS COMMITTEE FOR CLINICAL RESEARCH**

As the undersigned researchers participating in the study titled "Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations", we declare and undertake that we have read the latest version of the World Medical Association Declaration of Helsinki and the current Good Clinical Practices Guide / Good Laboratory Practices Guide published by the Ministry of Health, that the study will be conducted in accordance with the World Medical Association Declaration of Helsinki, GCP / GLP, that we assume all legal and financial responsibilities that may arise in the study, and that all units and staff participating in the study have been informed about the study.

Responsible Researcher:  
Asst. Professor Bedreddin Cavlı

Signature

Assistant Researcher  
Reacher Asst. Şeyma Kale

Signature

Counsellor  
Asst. Professor Necmiye Şengel

Signature

Counsellor  
Professor Ergun Yücel

Signature



**COMMITMENT**  
**KÜTAHYA UNIVERSITY OF HEALTH SCIENCES**  
**CHAIRMAN OF THE ETHICS COMMITTEE FOR CLINICAL RESEARCH**

**Title of the Study:** Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations

During the above-mentioned research, I undertake that no procedure that is not included in the research budget and that will impose an additional burden on the volunteer or the social security institution will not be applied and that I will fulfil my responsibilities in this regard.

**Research Responsible**

**Name-Surname-Title**

Asst. Professor Bedreddin CAVLI

**Signature**

**Date:**



**RESPONSIBLE RESEARCHER COMMITMENT FOR THE PROTECTION OF PERSONAL DATA**

This confidentiality undertaking ("Undertaking") has been signed between Kütahya Health Sciences University Oral and Dental Health Application and Research Centre ("Centre") located at İstiklal Neighbourhood Lala Hüseyin Pasha Street No:271 and the principal investigator [Dr. Bedreddin Cavlı] residing at [KSBÜ Oral and Dental Health Application and Research Centre Department of Oral, Dental and Maxillofacial Surgery].

With the Letter of Undertaking, the Employee irrevocably accepts, declares and undertakes the following matters, fully understanding and assimilating the consequences.

**MATTER 1**

**PROTECTION OF PERSONAL DATA**

a) Within the scope of the relationship established between the Centre and the Responsible Researcher, the Centre processes the personal data of all employees and patients as a data processor in accordance with the General Data Protection Regulation No. 6698 ("GDPR") in order to fulfil its obligations arising from the relevant legislation, especially Law No. 2547, to protect its justified and legitimate interests regarding the management of the Centre and scientific research, to fulfil its obligations to authorised third parties, competent administrative and judicial bodies, public institutions and

organisations, and to ensure data security, and may be transferred to third parties, especially authorized public institutions and organisations, within the scope of Article 8 of the GDPR

b) The scientific research officer and the entire team involved in the study will show the highest level of sensitivity and care regarding the processing and protection of personal and special quality personal data that they have learnt due to their duties and made available to them. In the event that the employee causes the disclosure of personal data or in case of security vulnerability, cyber-attack, data leakage or accidental loss or destruction of data in any way, the employee accepts, declares and undertakes that he / she will notify Kütahya University of Health Sciences, which has the title of data controller ("Data Controller") and the persons authorised by the Data Controller immediately and in writing from the date he / she becomes aware of the event in question.

c) The Principal Investigator and the entire team involved in the study for the research titled "Assessing the Frequency of Trigeminocardiac Reflex in Maxillary and Mandibular Cyst Operations", agrees, declares and undertakes that they will not illegally record the personal data of any person during and after the research, that they will anonymise all data to be used by the patients and destroy them after the end of the data usage period, that they will forward the records regarding the destruction to the Centre, and that they will not illegally give, disseminate or seize the personal data of any person. The responsible researcher and the entire team involved in the study accept and declare that they are aware that the acts in question constitute a criminal offence under the Turkish Penal Code.

RESPONSIBLE RESEARCHER DECLARATION

Asst. Professor Bedreddin Cavlı

RESEARCHER DECLARATION

Research Assistant Şeyma Kale