REPUBLIC OF TURKEY
ISTANBUL UNIVERSITY INSTITUTE of HALTH SCIENCES
DEPARTMENT OF ORAL AND MAXILLOFACIAL RADIOLOGY

RESEARCH PROTOCOL

Number of Protocol: 2019/73 **Date: 09/09/2019**

NAME OF THE RESEARCH	Investigation of the Reliability of Ultrasonography Usage in the Diagnosis of Temporomandibular Joint Diseases: A Prospective Study

RESOURCES OF THE RESEARCH AND RATIONALE	Today, a significant increase in the prevalence of temporomandibular joint diseases is observed.In addition to the basic clinical examination, there are several methods and techniques for the diagnosis of temporomandibular joint diseases. Magnetic resonance imaging is considered the gold standard in the evaluation of the articular disc as well as soft tissues. Computed tomography is used to diagnose bone lesions such as bone erosion, fractures, postoperative deformities, and deformities of the adjacent temporal bone. All of these methods have limitations. Ultrasound imaging of the joints and surrounding soft tissues is an alternative method for the diagnosis of temporomandibular joint diseases(1). However, the use of ultrasonography in the diagnosis of temporomandibular joint diseases is rare, but although there are several reports suggested in the literature, it is less expensive, less time consuming and easy to apply than other conventional imaging tools such as magnetic resonance imaging, arthrography and computed tomography scanning. recently gained attention and importance in terms of both research and patient care(2,3). The main expectation regarding the use of ultrasound devices in the diagnosis of temporomandibular joint diseases is the use of this method as a screening test. Magnetic resonance imaging, which is associated with exposure to magnetic fields, is very expensive, not found in most medical facilities, and is impossible in patients with claustrophobia. Computed tomography and cone beam computed tomography do not show soft tissues such as joint disc. Computed tomography scans are not performed more than once or twice a year due to exposure to x-rays. Panoramic radiographs available in many dentist clinics show only very advanced changes in the temporomandibular joint. Accurate diagnosis of temporomandibular diseases is not possible only with clinical examination(1).

	1. Klatkiewicz, T., et al., Ultrasonography in the Diagnosis of Temporomandibular Disorders: A Meta-Analysis. Med Sci Monit, 2018. 24: p. 812-817. 2. Su, N., et al., Diagnostic value of ultrasonography for the detection of disc displacements in the temporomandibular joint: a systematic review and meta-analysis. Clin Oral Investig, 2018. 22(7): p. 2599-2614. 3. Melis, M., S. Secci, and C. Ceneviz, Use of ultrasonography for the diagnosis of temporomandibular joint disorders: a review. Am J Dent, 2007. 20(2): p. 73-8.

PURPOSE OF THE RESEARCH	In the literature, there are not many studies on the diagnostic value of the use of ultrasonography in the diagnosis of temporomandibular joint diseases in dentistry. In this study, it is aimed to contribute to the literature in terms of revealing the reliability of the use of ultrasonography in the diagnosis of temporomandibular joint diseases.

BENEFITS EXPECTED AT THE END OF THE RESEARCH	By revealing the efficacy and reliability of ultrasonography in the diagnosis of temporomandibular joint diseases, to eliminate the disadvantages of MR and other imaging methods.

RESEARCH METHOD	Functional joint examination and ultrasonographic examination (USG) will be applied to all volunteers who will participate in the research. In the USG application, when the mouth is open and closed, the right and left joint intervals will be measured and a note will be taken. At the same time, right and left masseter muscle thicknesses will be measured separately at free-closing and tight-closing and a grade will be taken for all groups.. Volunteers to participate in the research will be divided into 4 groups.(I,II,III,IV).For volunteers in group 1 with previously taken MR images, USG and MR findings will be compared. In volunteers in group 2, the values obtained using different probes (linear, hockeystick) will be compared. In the third group of volunteers, the values to be obtained by using the USG probe at different angles (horizontal / longitudinal) will be compared. In volunteers in group 4, the megahertz values of the probe are changed and the findings obtained by examining them separately will be compared. In addition to evaluating 4 groups separately, at the end of the research, USG data applied to all 4 groups will be

	analyzed by comparing all the findings obtained in functional joint examination.

Research Design

	Observational Research		Experimental Research					
Descriptive Research	Yes ☐							
		Yes ☐						Retrospective Research
		Yes X						Prospective Research
Analytical Research	Yes ☐							
		Yes ☐						Retrospective Research
		Yes ☐						Prospective Research
Controlled Research			Yes ☐					Blind Research
			Yes ☐					Double-blind Research
			Yes ☐					Open Research
				Yes ☐				
					Yes ☐			
						Yes ☐		
Uncontrolled Research							Yes ☐	
	Cross Sectional Research	Longitudinal Research	Randomized Controlled Research	Non-Randomized Controlled Research	Cross-Randomination	Before and After Research		

PROCESS

What are the damages, risks and process problems that can be encountered during the research?	NO
What are the measures that can be taken against them?	NO

SAMPLE INFORMATION

How was the number of volunteers to participate in the research determined? Explain	When calculating the sample size of our study, reference values in previous similar studies were taken into consideration. When similar dental studies are examined; (μ1-μ2) and sd values are seen to range from 0.01 to 0.05 (Odacı E. v.d, 2003). When determining the sample size of the study (α=0,05, 1-β=%80) $f(\alpha,\beta)$=7,85, sd =0,05 and (μ1-μ2) = 0,02 when taken, it is seen that the sample size is n = 100. It is planned to include 100 volunteers in our research.
Sampling method	Volunteers will be selected from patients who applied to our clinic and who have complaints of temporomandibular joints.

VOLUNTEER POPULATION INFORMATION

Volunteers' inclusion criteria	**-Patients over the age of 18 who apply with TMJ problems** **-Patients with pain in the joint and chewing muscle area**
Volunteers' criteria for exclusion from research	**-Syndromic patients** **-Patients under the age of 18** **-Patients with a history of orthognathic surgery** **-Pregnants** **-Antidepressant Users** **-Patients Using Removable Dentures** **-Patients who have had joint treatment in the past six months**

Age range	
☐	Child Age Group (0-17)
	Number:0
X	Over 18 years old
	Number:100
	Total:100
Sex	
X	Female
X	Male
	Total: 100

WHAT ARE THE DATA TOOLS USED IN THE RESEARCH?

	With the Information-Questionnaire
X	■ Self-answer
☐	■ Answering under observation
☐	■ Answering through the interviewer
X	Observation
☐	Laboratory Review
☐	Registration from the archive
☐	Other

WHICH STATISTICAL METHODS WILL BE EVALUATED	In our study, SPSS application will be used for statistical analysis. In evaluating the categorical variables, the Chi-Square test will be used to look for a difference between the groups. Normality control of continuous variables will be done with Kolmogorov-Smirnov test. Difference evaluations of continuous variables between groups will be made with Student's t test in data with normal distribution. Group comparisons for data that are not suitable for normal distribution will be performed with Mann Whitney U test. Descriptive statistics will be specified by giving mean, standard deviation, minimum and maximum values of all continuous variables. Frequency distributions and percentages of categorical variables will be specified.

RESEARCH BUDGET

Total research expenses	****** TRY
Source of research expenses	
☐	■ The researcher himself
	■ Supporting
X	o University (Scientific Research Projects Unit)
☐	o TÜBİTAK
☐	o DPT
☐	o Industry and Other Institutions

CENTERS PARTICIPATED IN THE RESEARCH

X	o Single Center
☐	o Multi Center

RESPONSIBLE RESEARCHER

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PLANNING TIME OF THE RESEARCH:

- Planned Start Date**: 01.01.2020**
- Planned End Date : **01.01.2021**

THE PERSON TO BE CONTACTED ABOUT THE PROJECT:

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