31.12.2025

INFORMED CONSENT FORM

Title of the Study

EVALUATION OF ELECTRICAL AND THERMAL PULP SENSORY THRESHOLDS AND MASSETER INHIBITORY REFLEX RESPONSES IN PATIENTS WITH DIABETIC POLYNEUROPATHY

Control Group

You are invited to participate in a research study described below. Your decision to participate or not is entirely voluntary. Before deciding whether to participate, it is important that you understand why the research is being conducted, how your information will be used, what participation involves, as well as the possible benefits, risks, or any potential discomforts associated with the study.

Please take the time to read the following information carefully. If you decide to participate in the study, you will be asked to sign the Informed Consent Form. You are free to withdraw from the study at any time without any obligation or penalty.

No payment will be provided for participation in this study, and you will not be asked to make any financial or material contribution. All materials used in the study and any related expenses will be covered by the researcher.

STATEMENT THAT THIS IS A RESEARCH STUDY

This study will be conducted at the Departments of Neurology and Endodontics of Bezmialem Vakıf University. It is a research study that aims to compare electrical and thermal dental pulp sensibility test responses and masseter inhibitory reflex responses in patients with diabetic polyneuropathy with those of healthy individuals.

SUBJECT AND PURPOSE OF THE STUDY

This study will be conducted at the Departments of Neurology and Endodontics of Bezmialem Vakıf University and aims to evaluate neural responses of the dental pulp in patients with diabetic polyneuropathy.

In this research, dental pulp responses will be assessed using **electric pulp testing (EPT)** and **thermal (cold) pulp testing**, and these responses will be correlated with **masseter inhibitory reflex (MIR)** responses. The findings are expected to help clarify the effects of impaired nerve conduction on the oral and dental system in patients with diabetic polyneuropathy.

The results of this study aim to contribute to accurate diagnosis, appropriate anesthesia planning, and improved treatment outcomes in dental care for diabetic patients. By scientifically demonstrating

changes such as reduced pulpal sensibility or delayed reflex responses observed in diabetic individuals, this study seeks to support more personalized endodontic treatment approaches.

Approximately **108 volunteer participants** aged between **25 and 65 years** are planned to be included in the study. Participants will be divided into three groups: **mild diabetic polyneuropathy**, **severe diabetic polyneuropathy**, and **healthy control** groups.

This study is observational in nature. Participants will not be randomly assigned to groups, and no treatment or medication will be administered as part of the study.

EXPECTED DURATION OF PARTICIPATION

The total duration of participation in the study for each volunteer is expected to be approximately **0–10 days**.

ESTIMATED NUMBER OF PARTICIPANTS

The estimated number of volunteers expected to participate in this study is **108**.

TREATMENTS TO BE APPLIED IN THE STUDY

No treatment will be administered to participants as part of this study. All procedures performed within the scope of the research are **diagnostic tests and measurements**.

Following an intraoral examination, the following procedures will be applied to participants:

1. **Cold Pulp Test:**
   To evaluate the tooth's response to thermal stimulation, a cooling agent applied to a cotton pellet (e.g., Endo-Ice) will be briefly placed on the tooth surface.
2. **Electric Pulp Test (EPT):**
   To assess pulp vitality, a short-duration, low-intensity electrical stimulus (not exceeding **30 mA**) will be applied to the tooth surface using the Digitest 2 device.
3. **Masseter Inhibitory Reflex (MIR) Measurement:**
   Surface electrodes will be placed on the facial muscles, and the electrical activity (EMG signal) of the masseter muscle in response to electrical stimulation will be recorded.

All procedures are **painless, non-invasive**, and safe diagnostic tests routinely used in clinical practice. These tests are not expected to cause permanent damage, pain, or tissue injury. Any sensitivity that may occur is temporary. If the participant experiences discomfort, the procedure will be stopped immediately.

The total duration of all procedures is expected to be approximately **30–45 minutes**.

PROBABILITY OF RANDOM ASSIGNMENT TO DIFFERENT TREATMENT GROUPS

This study is observational in nature. Participants will not be randomly assigned to any study group, and no treatment or medication will be administered as part of the study.

EXPERIMENTAL ASPECTS OF THE STUDY

The study will be conducted on volunteers aged between **25 and 65 years** who are classified as having **mild diabetic polyneuropathy**, **severe diabetic polyneuropathy**, or being **healthy individuals**, based on their systemic condition and neurological evaluations.

Participants must have at least one **vital anterior tooth** that is free of restorations and caries.

In all participants, dental pulp vitality will be assessed using **electric pulp testing (EPT)** and **thermal (cold) pulp testing**, while **masseter inhibitory reflex (MIR)** responses will be evaluated using **surface electromyography (EMG)**.

POTENTIAL RISKS OR DISCOMFORTS TO THE PARTICIPANT

All procedures performed in this study consist of **non-invasive diagnostic tests** that do not compromise body integrity. Participants may experience **temporary and mild discomforts**.

During the **electric pulp test (EPT)**, a brief, low-intensity electrical stimulus applied to the tooth surface may cause a mild pricking or tingling sensation. During the **cold pulp test**, short-lasting cold sensitivity of the tooth may occur; this sensation typically resolves spontaneously shortly after the test is completed.

During **masseter inhibitory reflex (MIR)** measurement, participants may feel mild pressure or tension in the areas where surface electrodes are placed. Rarely, participants may experience brief muscle contraction or mild fatigue during the testing procedures.

INFORMATION REGARDING EXPECTED BENEFITS

If no direct clinical benefit to the participant is reasonably expected from participation in this study, the participant will be informed of this situation.

ALTERNATIVE METHODS OR TREATMENT OPTIONS AND THEIR POSSIBLE BENEFITS AND RISKS

This study does not involve any direct therapeutic intervention. However, the findings obtained are expected to provide valuable scientific data regarding dental pulp nerve conduction and reflex responses, particularly in patients with diabetic polyneuropathy. These data may contribute to accurate diagnosis, appropriate anesthesia planning, and improved treatment outcomes in future dental care.

If the participant chooses not to take part in this study, they may continue their dental examinations and treatments within the scope of routine clinical practices at the Faculty of Dentistry of Bezmialem Vakıf University.

Although participation in this study does not provide a direct therapeutic benefit to the participant, it may offer indirect benefits by contributing to personal diagnostic evaluation and treatment planning. The procedures applied in this study (electric pulp testing, cold pulp testing, and masseter inhibitory reflex measurement) are considered low-risk and may cause only temporary discomfort. No permanent side effects or harm are expected as a result of these procedures. The participant may request discontinuation of the procedures at any time.

COMPENSATION (INSURANCE) AND/OR MEDICAL TREATMENT, IF REQUIRED BY RELEVANT REGULATIONS

As this study is not conducted for therapeutic purposes and involves minimal risk, no additional research insurance is required. In the event of any unexpected situation, necessary medical care will be provided under the responsibility of Bezmialem Vakıf University.

COST OF PARTICIPATION

There will be no financial cost to you for participating in this study, and you will not receive any payment for your participation.

RESPONSIBILITIES OF THE PARTICIPANTS

Participants taking part in this study are expected to fulfill the following responsibilities:

1. To attend the scheduled appointments determined by the research team on time and to participate regularly in study sessions.
2. To inform the research team of any changes in their health status, medications, or systemic conditions during the study period.
3. To follow the instructions provided during measurement procedures (e.g., maintaining jaw position, avoiding clenching or speaking) and to comply with the researcher's guidance.
4. To immediately report any discomfort, pain, or anxiety experienced during the tests and to request termination of the procedure if desired.
5. To provide accurate and complete information, with the understanding that all data obtained within the scope of the study will be kept confidential.

Participation in this study is voluntary. The participant may refuse to participate or withdraw from the study at any time, without any penalty or loss of rights.

All records that may reveal the participant's identity will be kept confidential and will not be disclosed to the public. Even if the study results are published, the participant's identity will remain confidential.

Monitors, auditors, ethics committee members, institutional representatives, and other relevant health authorities may have direct access to the participant's original medical records when required by regulations. By signing the written informed consent form, the participant or their legal representative grants permission for such access, with the assurance that confidentiality will be maintained.

If new information related to the study becomes available that may affect the participant's willingness to continue participation, the participant or their legal representative will be informed in a timely manner.

CONTACT INFORMATION

For further information regarding the study, the participant's rights, or any adverse events related to the study, the participant may contact the following individuals at any time (24/7):

- **Prof. Dr. Mehmet Burak Güneşer:** +90 554 800 3720
- **Dentist Tuğçe Aras:** +90 530 118 9449

CIRCUMSTANCES OR REASONS THAT MAY LEAD TO TERMINATION OF PARTICIPATION

Participation in this study may be terminated under the following circumstances:

1. **Voluntary withdrawal by the participant.**
   The participant has the right to withdraw from the study at any time without providing any reason. Withdrawal from the study will not affect current or future medical care in any way, and no justification is required.
2. **Development of discomfort, pain, anxiety, or stress during the study** and the participant's decision not to continue with the procedures.
3. **Occurrence of any condition that may affect the study outcomes**, such as the development of a new systemic disease, acute infection, dental problem, or initiation of medication use.
4. **Termination of participation by the research team** if continuation of the study is deemed inappropriate for safety or ethical reasons.
5. **Non-compliance with the study protocol**, including failure to attend scheduled appointments, lack of cooperation during measurements, or provision of incomplete or inaccurate information, at the discretion of the investigator.
6. **Suspension or termination of the study** based on a decision by the ethics committee or institutional administration.

Access to study-related research outcomes will be provided after completion of the study.

INFORMATION REGARDING BIOLOGICAL MATERIALS TO BE COLLECTED

No biological samples (such as blood, saliva, tissue, cells, DNA, etc.) will be collected from participants within the scope of this study. Only non-invasive diagnostic tests (electric pulp testing, cold pulp testing, and masseter inhibitory reflex measurement) will be performed.

All data recorded during the study will be obtained electronically in numerical form (e.g., voltage, millivolts, latency, duration). Data analysis will be conducted within the Department of Endodontics, Faculty of Dentistry, Bezmialem Vakıf University. Personal information will be stored using a de-identified coding system. The code key containing identifying information will be kept in a locked file by the principal investigator only and will not be shared with third parties.

STATEMENT OF CONSENT TO PARTICIPATE

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I understand that my participation in this study is entirely voluntary and that I may withdraw from the study at any time without providing any reason, and that this will not affect my medical treatment or my right to receive healthcare services. All of my questions have been answered satisfactorily. I voluntarily agree to participate in this study of my own free will.

Participant Full Name:
Date and Signature:
Phone Number:

Legal Guardian (if applicable) Full Name:
Date and Signature:
Phone Number:

Witness Full Name:
Date and Signature:
Phone Number:

Researcher Full Name:
Date and Signature:
Phone Number:

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