Faculty of Dentistry – Ain Shams University

Ethics of Scientific Research Committee (FDASU-REC)

Informed Consent Form

Participant Name:	_____	Age:	_____
National ID / Code (optional):	_____	Sex:	_____
Address:	_____		
Telephone:	_____	Mobile:	_____

Study Title (Official): The Ability of Brain Waves Activity to Detect Patient Susceptibility to Post-Operative Pain

Ethics Approval: FDASU-REC (Meeting No. 120, 22-Dec-2021) – Approval Serial No. (FDASU-Rec IM122127)

Purpose of the Study

This study aims to investigate whether the frequency of resting-state alpha brain waves can help predict the intensity of pain after single-visit root canal treatment (endodontic treatment).

Why You Are Being Asked to Participate

You are being invited because you may meet the study eligibility criteria (age 20–40 years and a vital mandibular first molar with signs and symptoms of acute irreversible pulpitis that is indicated for single-visit root canal treatment).

Number of Participants

A total of 100 participants will be included (50 participants per group).

Study Location

Endodontics Department Clinic, Faculty of Dentistry, Ain Shams University.

Study Procedures

• If you agree, you will receive the required root canal treatment as planned. This treatment is standard clinical care and will be performed in a single visit whenever possible.

• You will be asked to wear a non-invasive EEG headset/device (EMOTIV® EPOC X) to record resting-state alpha brain-wave activity:

• • before the root canal treatment (baseline recording),

• • immediately after the root canal treatment.

• You will be asked to record your pain intensity using a Visual Analogue Scale (VAS) every 6 hours after treatment (for the first 72 hours), following the provided instructions.

• Your EEG recordings and pain scores will be analyzed statistically to evaluate the relationship between alpha-wave frequency and post-treatment pain intensity.

Eligibility Criteria

Inclusion criteria:

• Age 20–40 years.

• Vital mandibular first molar with signs and symptoms of acute irreversible pulpitis and indicated for single-visit root canal treatment.

• No medicinal therapy taken after endodontic treatment (as per study instructions).

• Able (physically and mentally) to record pain intensity every 6 hours using the VAS.

Exclusion criteria:

• Systemic disease or neurogenic disease that contraindicates EEG use, or sensitivity to electrode materials.

• Cases where root canal treatment cannot be completed in a single visit (e.g., apical periodontitis, pulpal necrosis, chronic apical abscess).

• Use of analgesics within 72 hours after endodontic treatment.

Time Commitment

The clinical procedures are performed during your treatment visit. EEG recordings add additional time before and after treatment. You will also complete short pain recordings at home (VAS) every 6 hours for 72 hours.

Risks and Discomforts

EEG recording is non-invasive. Possible minor discomfort includes temporary pressure from the headset or mild skin irritation at electrode contact points. Root canal treatment and local anesthesia are standard procedures and may be associated with temporary post-operative pain or tenderness. If you experience any unexpected problems, please contact the research team.

Benefits

You will receive the required endodontic treatment. There may be no direct additional benefit to you from the EEG recordings. The results may help improve future understanding and management of post-endodontic pain.

Costs and Compensation

There are no additional costs to you for participating in this study. No financial compensation is provided.

Confidentiality

Your information will be kept confidential. Your data will be coded and stored securely, and only the research team will have access. Results may be published in scientific form, but you will not be identified.

Voluntary Participation and Right to Withdraw

Your participation is voluntary. You may refuse to participate or withdraw at any time without giving a reason and without affecting the care you receive.

Contact Information

If you have questions about the study, please contact:
Researcher / Principal Investigator: Ahmed Reda Abd El Rahman Hammad
Supervisors: Dr. Ahmed Abd El Rahman Hashem (Professor and Chairman), Dr. Mohamed Mokhtar Nagy (Professor of Endodontics), Dr. Mohamed Mohamed Elashiry (Lecturer of Endodontics)
Telephone: _____ **Email:** _____

Consent Statement

I have read (or had read to me) the information in this consent form. I have had the opportunity to ask questions, and my questions have been answered. I understand that my participation is voluntary and that I can withdraw at any time without affecting my treatment. By signing below, I agree to participate in this study.

Participant Name:	_____	Signature:	_____
Date:	____ / ____ / _____	Time:	_____
Witness Name (if needed):	_____	Signature:	_____
Researcher Name:	Ahmed Reda Abd El Rahman Hammad	Signature:	_____

Participant Copy

A copy of this consent form will be provided to the participant.