

Patient Information with Informed Consent Form

1. Study Title:

The importance of oral mucosal screening in the prevention of oral cancer.

2. Study objectives:

1. To determine the prevalence of potentially malignant lesions of the oral mucosa in high- and low-risk individuals using conventional examination (visual and palpation) and fluorescence methods with Oralitest.
2. To evaluate the detectability of potentially malignant lesions of the oral mucosa using conventional examination compared to fluorescence methods.

3. Study Description:

The study will be conducted among patients who consent to complete a questionnaire and participate in the study—those who visit the Department of Oral Mucosal and Periodontal Diseases at the University Dental Center of the Medical University of Warsaw (CM WUM) for the prevention and treatment of oral mucosal and periodontal diseases. Each participant will be asked to complete a proprietary questionnaire designed for the purposes of this study, consisting of questions regarding risk factors for the development of potentially neoplastic lesions and oral cancer. This will be followed by the following procedures in sequence: a conventional external and intraoral examination, and an examination of the oral mucosa using fluorescence methods with the selected Oralitest device. The use of the fluorescence method requires light from a curing light. When epithelial tissue is exposed to light of a specific wavelength, fluorescence examination can reveal changes in its structure—all the way down to the basement membrane, where precancerous lesions typically originate. This makes it possible to clearly distinguish diseased, altered tissue—which appears as a darkened, irregular area—from the healthy background, which reflects light with a characteristic bright color. Both the clinical examination and the fluorescence examination will be conducted by a single dental hygienist—the project's author—according to a specific, standardized protocol covering the labial red and individual parts of the oral mucosa (mucosa of the lips, cheeks, hard and soft palate, gums, oropharynx, tongue, and floor of the mouth). In the clinical examination, the mucosa will be assessed for color, moisture, and the presence of the following lesions: spot/stain (white,

red, purple, black), papule, nodule, tumor, blister, vesicle, pustule, abrasion, erosion, fissure, ulcer, scale, scab, scar.

A lymph node palpation examination will also be performed according to a specific protocol: preauricular nodes, retroauricular nodes, parauricular node, and submandibular nodes. To assess oral hygiene, the API index will be determined, and the dentition and prosthetic restorations will be evaluated for areas where bacterial plaque can accumulate and for factors that irritate the mucous membrane. During the examination, using fluorescence methods with the Oralitest device, the oral mucosa will be assessed for the presence of lesions that may suggest dysplasia—dark, irregular, often asymmetrical spots that stand out clearly against healthy, green-glowing tissue. The presence of any lesions, their location and size, or any abnormalities in tissue fluorescence will be recorded in the oral mucosa examination chart. Patients in whom potentially malignant neoplastic changes are detected will be immediately referred for consultation with a periodontist.

4. Duration of the examination for each participant: approximately 30 minutes
5. Expected benefits of the study: the opportunity for a preventive examination of the oral mucosa for the early detection of potentially cancerous lesions, in a non-invasive manner.
6. Risks and inconveniences for the study participant: the inconvenience of keeping the mouth open
7. Description of insurance coverage: Application No. 2024/EL3345 with a coverage period from May 15, 2024, to May 14, 2027

Sensitive data will be stored as scientific research records in anonymized form at the Department of Mucosal and Periodontal Diseases of the University Center for Dentistry, Medical Center of the Medical University of Warsaw, prior to their analysis in electronic form.

I, the undersigned,

..... hereby declare that I have read and understood the above information regarding the described study, I had the opportunity to ask questions, and I received comprehensive, satisfactory answers to my questions. I voluntarily consent to participate in this study and am aware that I may withdraw my consent to continue participating in the clinical trial at any time without giving a reason. By signing this consent form, I do not waive any of my rights. I will receive one of the two copies of this form, signed and dated. By signing this document, I also confirm that I have been informed about how the study data will be processed, that this data will be verified by

comparing it with my medical records, and that this data is collected solely for the purpose of scientific analysis of the study. I consent to the processing of my data in this study in accordance with the law in force in Poland (Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC). I consent to the transfer of my anonymized data to other countries, both within and outside Europe.

The data analyzed by the relevant authorities, representatives of the Ministry of Health, government agencies, and Bioethics Committees will be available only in anonymized form. I have been informed that if I withdraw my consent to participate in the study, the data collected to date may be used and processed as part of the study database. I have been informed that, in accordance with Article 13 of the General Data Protection Regulation of April 27, 2016:

8. The controller of my personal data is the Medical University of Warsaw, located in Warsaw at ul. Żwirki i Wigury 61,

9. The Data Protection Officer at the Medical University of Warsaw is Marcin Wójcik, phone number 22-57-20-240, email address iod@wum.edu.pl.

10. My personal data will be processed for the purpose of conducting the study: "The Importance of Mucosal Screening in the Prevention of Oral Cancer" at the Department of Mucosal and Periodontal Diseases of the University Center Dentistry, Medical Center of the Medical University of Warsaw, pursuant to Article 9(2)(a) of the General Data Protection Regulation of April 27, 2016,

11. My personal data may be disclosed exclusively to:

- persons authorized by the controller to process personal data,
- processors under a data processing agreement,
- representatives of domestic, foreign, or international institutions supervising the clinical trial, provided that the conditions set forth in Chapter V of the General Data Protection Regulation of April 27, 2016 ,
- other entities authorized under applicable law

12. My personal data will be stored only for the period required by applicable law,

13. I have the right to access my data, the right to have it rectified, erased, or its processing restricted, the right to data portability, the right to object, and the right to withdraw my consent at any time,

14. I have the right to file a complaint with the Personal Data Protection Office if it is justified that your personal data is being processed by the controller in violation of the General Data Protection Regulation of April 27, 2016;

15. Providing personal data is voluntary;

16. Decisions will not be made by automated means, and I will not be subject to profiling.

I have read the terms and conditions of the civil liability insurance covering the sponsor and the investigator for damages caused in connection with the conduct of a clinical trial pursuant to policy number 2024/EL/3345 issued by the Insurance Company, and I accept them.

Patient:

.....

First and last name (in block letters)

Signature Date of signature (by the patient)

I hereby declare that I have discussed the proposed test with the patient using clear, simple language, and have provided information regarding the nature and significance of the test.

Person obtaining consent for the test

.....

First and last name (in block letters)

Signature Date of signature

Patient Information Form with Informed Consent Form for the study, version no. 1 dated March 26, 2024.