

STUDY PROTOCOL

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1. Study Title

The significance of oral mucosal screening examinations in the prevention of oral cancer.

2. Current State of Knowledge

According to the World Health Organization (WHO) Global Oral Health Status Report published in 2022, oral cancer ranks as the sixteenth most common cancer worldwide. Men develop oral cancer more than 2.5 times more frequently than women (1). In Poland, oral cancer accounts for approximately 2.5% of all malignant neoplasms (2,8). Structural abnormalities of the oral mucosa, understood as pathological conditions affecting the oral cavity, may be associated with an increased risk of developing oral cancer.

The development of oral potentially malignant disorders (OPMD) is influenced by endogenous factors, including genetic predisposition, systemic diseases, and confirmed infection with oncogenic human papillomavirus (HPV) types, as well as exogenous factors such as cigarette smoking and the use of other tobacco products, alcohol consumption, mechanical trauma, and excessive exposure to sunlight (3,4,5).

According to the available literature, population-based screening programmes relying on visual examination of oral lesions may reduce mortality from oral cancer by approximately 24%. Furthermore, these programmes improve the early detection of potentially malignant lesions at the dysplastic stage. As non-invasive and socially acceptable methods, they may increase participation in screening programmes while simultaneously reducing the costs of preventive healthcare (5,6,8,12,13).

References

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5. El-Naggar AK, Chan JKC, Grandis JR, Takata T, Slootweg PJ (Eds.). *WHO Classification of Head and Neck Tumours*. Lyon: International Agency for Research on Cancer (IARC); 2017.
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4. Methodology

1. Study Design

1.1 Study Type

Observational clinical case–control study

2. Study Population

The study will be conducted among patients who provide informed consent to complete a questionnaire and participate in the study. Participants will be recruited from patients attending the Department of Oral Mucosal Diseases and Periodontology, University Dental Centre, Medical University of Warsaw, for the prevention and treatment of oral mucosal and periodontal diseases.

2.1 Inclusion and Exclusion Criteria

Inclusion criteria

- Age ≥ 18 years
- Female or male

Exclusion criteria

- Age below 18 years
- Patients with previously diagnosed and actively treated oral potentially malignant disorders (OPMD)

During the first stage of the study, the study group will consist of patients classified as being at high risk of developing oral potentially malignant disorders (OPMD) and oral cancer, based on questionnaire responses indicating one or more of the following risk factors:

- age over 40 years;
- cigarette smoking or the use of other tobacco products;
- excessive alcohol consumption;
- confirmed HPV infection;
- frequent trauma to the oral mucosa;
- use of immunosuppressive medication;
- a personal or family history of malignant neoplasms affecting the upper respiratory tract or gastrointestinal tract;
- poor oral hygiene (Approximal Plaque Index, API >70%).

The control group will consist of patients who do not meet the criteria for classification into the high-risk group for oral potentially malignant disorders (OPMD) and oral cancer.

Each participant will be asked to complete an original questionnaire specifically designed for this study, consisting of questions concerning risk factors associated with the development of oral potentially malignant disorders (OPMD) and oral cancer (Appendix 1).

Subsequently, each participant will undergo:

- a conventional extraoral and intraoral clinical examination, followed by
- an oral mucosal examination using fluorescence imaging with the Oralitest device.

Both the conventional clinical examination and the fluorescence examination will be performed by a single investigator—a registered dental hygienist and principal investigator of the study—according to a standardized examination protocol covering the vermilion border of the lips and all anatomical regions of the oral mucosa, including:

- labial mucosa,
- buccal mucosa,
- hard palate,
- soft palate,
- gingiva,
- oropharyngeal mucosa,
- tongue,
- floor of the mouth.

During fluorescence examination using the Oralitest device, the oral mucosa will be assessed for lesions suggestive of epithelial dysplasia, characterized by dark, irregular, and frequently asymmetrical areas that contrast distinctly with the surrounding healthy tissue, which exhibits normal green autofluorescence.

The presence of any lesion, together with its location, size, and any abnormalities in tissue autofluorescence, will be recorded in the oral mucosal examination chart.

Participants in whom potentially malignant lesions are identified will be referred immediately for specialist consultation with a periodontist.

2.2 Sample Size

The required sample size was determined based on a statistical power analysis.

The calculated statistically significant sample size is 1,383 participants.

3. Study Endpoints

The primary study endpoints are measurable parameters considered clinically significant for comparisons between the study groups and used as the basis for sample size calculation:

- **Specificity:** 0.90
- **Estimated prevalence:** 2.5%
- **Epsilon parameter (margin of error):** 0.10
- **Confidence level:** 95%

5. Expected Benefits of the Study

The study is expected to provide an opportunity for non-invasive preventive screening of the oral mucosa, enabling the early detection of oral potentially malignant disorders (OPMD) and other lesions associated with an increased risk of oral cancer.

6. Risks and Potential Inconveniences for Participants

Participation in the study involves minimal risk.

The only anticipated inconvenience is the need for participants to keep their mouths open throughout the clinical and fluorescence examinations.

7. Study Duration

25 May 2026 – 14 May 2027

8. Duration of Participation for Each Subject

Approximately 30 minutes.

9. Insurance Information

The study is covered by insurance under Application No. 2024/EL3345, valid for the study period from 15 May 2026 to 14 May 2027.

10. Study Protocol Version

Version 1

Date of preparation: 15 May 2026

Data Protection

Sensitive data collected during the study will be anonymised and stored as scientific research documentation at the Department of Oral Mucosal Diseases and Periodontology, University Dental Centre, Medical University of Warsaw, prior to electronic data analysis.