

A public survey about oral cancer in Northern Italian adults

Submission date 16/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/12/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Oral cancer represents one of the most common malignant tumours in the world with an incidence that has tripled in the last 3 years. Mortality of patients with oral cancer is among the highest in oncology. Currently, 5-year survival is less than 50%, and the necessary surgical, radiotherapy and chemotherapy therapies are highly invasive, complex, and debilitating. Today, the only effective prevention strategies aim to control the risk factors to reduce their onset and make an early diagnosis to improve the prognosis. For there to be an early diagnosis, it is essential that people are aware of the pathology including early signs, symptoms, and specialists to contact in case of doubt. Currently, different articles investigate the population's knowledge of oral cancer in different parts of the world, such as China, Australia, Spain, and Kuwait. However, most of these studies focused on a selected population, such as dental patients or university students. According to their results, controversial data based on the different geographical areas was highlighted and in general, a low level of awareness and knowledge about the pathology, signs, symptoms, and risk factors was highlighted. To the researcher's knowledge, to date only one previous study investigated the awareness of the pathology in the Italian population, focusing on a single city located in the northeast part of Italy (Trieste). Furthermore, the study was based on an online questionnaire and as highlighted by the study's authors, more research in different Italian geographical areas is required. The first aim of the present study will be to investigate the general population's knowledge of oral cancer in the Piedmont area (northwest Italian region) as well as its risk factors and manifestations. The second aim will be to improve the population's awareness by releasing an informative brochure on the topic to patients who will be enrolled in the study.

Who can participate?

Adult patients aged between 18 and 90 years old who visit pharmacies in the Piedmont area of Italy

What does the study involve?

Each questionnaire, without any sensitive data, will be designed as a multichoice questionnaire with a series of 12 questions to acquire data about the population's knowledge of oral cancers, including the following topics:

1. Background-related data (age, gender, educational background, frequency of dental check-

ups, smoke habits, urban vs rural resident)

2. Oral cancer awareness data (whether they have never heard about oral cancer and the way)

3. Knowledge about oral cancer (risk factors, whether the oral cancer is a malignant or benignant tumour, survival rate, early diagnosis, age of onset, signs and symptoms, specialists to contact in case of suspicions)

4. Information about the channel they would consider more valuable to share more information about oral cancer

What are the possible benefits and risks of participating?

There are no risks of participating. We supposed that most of the individuals did not receive counseling on oral cancer by dentists, physicians, or other health care providers. The benefit will be the improvement in oral cancer knowledge in the Piedmont population.

Where is the study run from?

University of Turin (Italy)

When is the study starting and how long is it expected to run for?

January 2023 to December 2024

Who is funding the study?

Investigator initiated and funded (Italy)

Who is the main contact?

Prof Paolo Giacomo Arduino, paologiacomo.arduino@unito.it

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Knowledge and understanding of oral cancer in adults: a cross-sectional survey in North-Western Italy

Acronym

KnowOC

Study objectives

Knowledge of oral cancer is very low in the common population

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 11/09/2023, Ethical Review Board of the University of Turin (Via Verdi 8, Turin, 10100, Italy; +39 116704377; Staff.cba@unito.it), ref: Prot. n. 0494208

Study design

Cross-sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a participant information sheet.

Health condition(s) or problem(s) studied

Oral cancer

Interventions

The aim of the study is to verify the knowledge on oral cancer and to assess possible differences in awareness and information basing on different demographic and subject-related factors.

An anonymous survey will be provided to random subjects attending selected pharmacy in Piedmont region. Forty-five pharmacies (n = 45) will be selected for the purpose.

Twenty anonymous questionnaires (n = 20) will be provided to each pharmacy for a total questionnaire number of 900 (n = 900). People who will go to the pharmacies and will meet the following inclusion/exclusion criteria will be asked on a volunteering basis to participate in the study and complete the questionnaire. Ten trained students of pharmacology will provide the questionnaire. Each questionnaire, without any sensitive data, will be designed as a multi-choices questionnaire with a series of 12 questions to acquire data about the population's knowledge on oral cancers, including the following topics: (1) Background-related data (age, gender, educational background, frequency of dental check-ups, smoke habits, urban vs rural resident); (2) oral cancer awareness data (whether they have never heard about oral cancer and the way); (3) knowledges about oral cancer (risk factors, whether the oral cancer is a malignant or benignant tumour, survival rate, early diagnosis, age of onset, sign and symptoms, specialists to contact in case of suspicions); (4) information about the channel they would consider more valuable to share more information about the oral cancer.

At the end of the study, statistical analysis will be performed in order to evaluate the influence of different demographic variables on knowledge of oral cancer and its risk factors.

Intervention Type

Other

Primary outcome measure

Oral cancer knowledge measured using a questionnaire at a single time point.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/01/2023

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. Age ≥ 18 years old
2. People who go to the pharmacies for any reason
3. Agreement to participate in the study

Participant type(s)

Population

Age group

Mixed

Lower age limit

18 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

900

Key exclusion criteria

1. Aged <18 years old
2. Cognitive deficit
3. Refusal to participate in the study
4. People with an existing diagnosis of oral cancer

Date of first enrolment

01/10/2023

Date of final enrolment

01/06/2024

Locations**Countries of recruitment**

Italy

Study participating centre

University of Turin, CIR-Dental School

Via Nizza 230

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Sponsor information**Organisation**

University of Turin

Sponsor details

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Sponsor type
University/education

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<http://en.unito.it/>

ROR
<https://ror.org/048tbm396>

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact and peer-reviewed journal

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication