Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The accuracy of non-invasive method of oral squamous cell cancer diagnosis based on the difference in temperature using IR sensor

Protocol summary

Study aim

The accuracy of non-invasive method of oral squamous cell cancer diagnosis based on the difference in temperature using IR sensor

Design

The experimental group included 10 patients with oral squamous cell carcinoma referring to the Institute Cancer and control group included 10 healthy individuals without history of any oral lesions

Settings and conduct

Place: Cancer Institute of Imam Khomeini Hospital in Tehran In this study, in order to detect oral squamous cell carcinoma using the temperature difference between the healthy area and the tumor area, a device was used which allowed entering the mouth and using the temperature distribution and recording it through a sensor sensitive to temperature was used noninvasively and accurately to detect tumor tissue in the mouth without taking samples from the tissue.

Participants/Inclusion and exclusion criteria

Inclusion criteria: in the test group all patients with oral squamous cell carcinoma referred to the institute Cancer of Imam Khomeini Hospital older than 10 years and in the control group all healthy people without any oral lesions greater than 10 years old that are able to understand the description and willingness to cooperate. People who do not undergo any treatment such as surgery, chemotherapy, radiotherapy, etc. to treat oral lesions. Exclusion criteria: people with acute infectious diseases or sweat glands diseases such as Ectodermal Dysplasia. Patients with hyperthermia at the examination time. Recurrent oral lesion.

Intervention groups

In case group, the temperature of the lesion and the opposite side temperature and in the control group, the temperature of the lateral side of the tongue was measured in two right and left (both healthy sides)

Main outcome variables

Non-invasive diagnosis of squamous cell carcinoma according to the difference in temperature with the use of IR sensor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181130041806N1**
Registration date: **2020-06-20, 1399/03/31**
Registration timing: **retrospective**

Last update: **2020-06-20, 1399/03/31**
Update count: **0**

Registration date

2020-06-20, 1399/03/31

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

2016-11-10, 1395/08/20

Actual recruitment end date

2018-01-25, 1396/11/05

Trial completion date
2018-01-25, 1396/11/05

Scientific title
The accuracy of non-invasive method of oral squamous cell cancer diagnosis based on the difference in temperature using IR sensor

Public title
The accuracy of non-invasive method of oral cancer diagnosis based on the difference in temperature using IR sensor

Purpose
Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:
In the experimental group, all patients with oral squamous cell carcinoma referring to Cancer Institute of Imam Khomeini Hospital greater than 10 years old In the control group, all healthy subjects without oral lesions greater than 10 years old

Exclusion criteria:
Having acute infectious diseases or sweat glands diseases such as Ectodermal Dysplasia Hyperthermia History of oral cancer in the same area (recurrent oral lesion)

Age
From **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
In the test group, the side has a lesion and the opposite side of the lesion in the mouth and in the control group, the lateral sides of tongue on the right and left
Actual sample size reached: **20**
More than 1 sample in each individual
Actual sample size in each individual: **2**
In the test group, the side has a lesion and the opposite side of the lesion in the mouth and in the control group, the lateral sides of tongue on the right and left

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Central of Tehran University of Medical Sciences, Qods St., Keshavarz Blvd.

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Tehran

Province
Tehran

Postal code
1417653761

Approval date
2016-08-21, 1395/05/31

Ethics committee reference number
IR.TUMS.VCR.REC.1395.473

Health conditions studied

1

Description of health condition studied
Oral squamous cell carcinoma

ICD-10 code
C06.9

ICD-10 code description
Malignant neoplasm of mouth, unspecified

Primary outcomes

1

Description
The temperature difference between the healthy area and the area with oral squamous cell carcinoma

Timepoint
At the beginning of the study before the biopsy

Method of measurement
Infrared sensor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The inclusion criteria were selected after searching the scientific literature and consulting oral medicine specialists and oncologists. The inclusion criteria for patients included all patients with OSCC presenting to the Cancer Institute of Imam Khomeini Hospital who were older than 10 years of age. Patients had to be able to understand the prescriptions given and had to be willing to participate in the study. Those with a

history of oral surgery, chemotherapy and radiotherapy of the head and neck were not included. Acute infections, diseases of sweat glands such as ectodermal dysplasia, recurrent oral cancer and hyperthermia at the time of examination were exclusion criteria; Also, Patients who did not resume their treatment or presented to other medical centers to resume their treatment and those who did not consent to undergo diagnostic procedures such as biopsy, and those who met the inclusion criteria but underwent surgery or initiated their radiotherapy prior to the onset of study were excluded as well. an intraoral device with temperature-sensitive sensor was used to accurately assess heat distribution and non-invasively detect OSCC based on the thermal difference between the healthy and tumoral tissues.The device has been designed with a small flexible head that can be used intraorally with easily access all areas in the oral cavity which is an advantage because the currently available thermographic devices that are used for cancer detection in other parts of body cannot be used intraorally. This device has high accuracy and records the temperature with 0.02°C accuracy and displays it on a monitor. Also, the device is equipped with an alert system, which beeps when the temperature of an area is higher than the defined normal oral temperature (38.1°C). The device has been designed according to the ergonomic dental principles and is easy to use for the clinicians. Also, it is portable and wireless and can be used anywhere without requiring a camera, a laptop or any other device. For the purpose of standardization, the participants were asked to refrain from eating, drinking and smoking for 30 minutes prior to testing. Also, in order to stabilize the metabolic activity of the human body, the participants were requested to sit in an upright position, in a well-lit room with optimal temperature and humidity for 20 minutes and relax. First, the body temperature was measured by an individual intraoral conventional mercury thermometer and recorded. Next, the patients were requested to slightly tilt their head backward while in a seated position. The device was then turned on and the sensor was held at a close distance from the approximate center of lesion, which according to the literature, has the highest temperature for about 30 seconds until the temperature displayed on the monitor stabilized. This value indicated the mean temperature of the lesion. The same was done for the contra-lateral healthy mucosa of the same patient, and the temperature was recorded as the control temperature. For the purpose of infection control, the tip of the device covered with disposable covers and changed for each patient. Temperature measurements were made by an expert oral medicine specialist who had been trained to use this device. Next, according to the opinion of an oncologist, all patients underwent incisional biopsy, which is the gold standard for detection of oral lesions

Category

Early detection

2

Description

Control group: The inclusion criteria for the control group were healthy individuals with no oral lesion and older than 10 years of age and had to be able to understand the prescriptions given and had to be willing to participate in the study. Those with a history of oral surgery, chemotherapy and radiotherapy of the head and neck were not included. Acute infections, diseases of sweat glands such as ectodermal dysplasia, oral cancer and hyperthermia at the time of examination were exclusion criteria.Since, the higher number of patients had OSCC of tongue compared with whom had OSCC of lips (4 to 1), in the next step the temperature of the lateral sides of the tongue (right and left) in 10 healthy controls was measured as explained in patient group.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

cancer Institute of Imam Khomeini Hospital

Full name of responsible person

Soheila Manifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Researcher
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to

make this available