ISRCTN14947812 https://doi.org/10.1186/ISRCTN14947812

Effects of radiotherapy on olfactory function in patients with head and neck cancer

Submission date
28/09/2025

Recruitment status
No longer recruiting

Registration date
29/09/2025

Overall study status
Completed

Last Edited
04/02/2026

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Head and neck cancer patients often receive radiotherapy as part of their treatment. While radiotherapy is effective in controlling cancer, it can also affect nearby structures, including the olfactory system. Loss of smell may reduce quality of life, but little is known about how radiotherapy dose to the olfactory region relates to long-term changes in smell function. This study aims to determine how many patients developed olfactory dysfunction after radiotherapy, and whether higher radiation doses were associated with a greater risk of smell loss. Secondary analyses explore changes in the Taiwan Smell Identification Test (TWSIT), a standardised smell test, scores over time, dose-response relationships, and potential threshold doses predictive of olfactory dysfunction.

Who can participate?
Adult patients with head and neck cancer who were scheduled for intensity-modulated radiotherapy (IMRT) at Chang Gung Memorial Hospital, Chiayi, Taiwan.

What does the study involve?
Participants were prospectively enrolled between January 2021 and December 2023. All participants completed the TWSIT, a standardised smell test, before treatment and again after radiotherapy at 1, 3, 6, and 12 months. Radiation dose to the olfactory structures was measured from radiotherapy treatment plans.

What are the possible benefits and risks of participating?
By clarifying the relationship between radiation dose and olfactory outcomes, this study may help doctors to better predict, explain, and potentially reduce smell-related side effects of head and neck cancer treatment in the future.

No risks provided at registration

Where is the study run from?
Chang Gung Memorial Hospital, Chiayi, Taiwan.

When is the study starting and how long is it expected to run for?
November 2020 to December 2023

Who is funding the study?
Chang Gung Medical Foundation, Taiwan.

Who is the main contact?
Dr Geng He Chang, genghechang@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Geng He Chang

ORCID ID
https://orcid.org/0000-0001-5939-9747

Contact details
No.8, W. Sec., Jiapu RD., Puzi City
Chiayi
Taiwan
61363
+886-5-3621000 ext.2076
genghechang@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Funding grant number CMRPG6L0041-3

Study information

Scientific Title
Prospective observational cohort study of radiotherapy dose to the olfactory region and subsequent olfactory dysfunction in head and neck cancer patients at Chang Gung Memorial Hospital

Acronym
OLFACT-RT

Study objectives

To investigate the relationship between radiation dose delivered to the olfactory region and the occurrence of olfactory dysfunction in patients with head and neck cancer receiving intensity-modulated radiotherapy (IMRT).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/11/2020, Chang Gung Medical Foundation Institutional Review Board (199 Tung Hwa North Road, Taipei, 10507, Taiwan; +886-3-3196200 ext.3705; tsengshui@cgmh.org.tw), ref: 202001923B0C501

Study design
Prospective observational cohort study single-centre study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Head and neck cancers (including nasopharyngeal carcinoma, nasal cavity cancer, oral cavity cancer, tonsil cancer, hypopharyngeal cancer, laryngeal cancer, parotid cancer and palate cancer)

Interventions
All participants received standard-of-care intensity-modulated radiotherapy (IMRT), with some patients also receiving concurrent chemotherapy as clinically indicated. No additional interventions were assigned by the investigators.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The proportion of participants with olfactory dysfunction (TWSIT <40) measured using the Taiwan Smell Identification Test (TWSIT, score range 0–48) at baseline (pre-RT), end of radiotherapy, and at 1, 3, 6, and 12 months post-RT

Key secondary outcome(s))
1. Change in olfactory function measured using the change in TWSIT scores (continuous 0–48) from baseline to end of RT and to 1, 3, 6, and 12 months post-RT
2. Dose–response relationship measured using the association between mean olfactory-region radiation dose (Gy) and change in TWSIT scores measured using radiotherapy treatment plans at one timepoint
3. Dose threshold exploration measured using the identification of potential radiation dose cut-off values predictive of olfactory dysfunction using ROC analysis, measured using radiotherapy treatment plans at one timepoint
4. Regression analysis of odds measured using the logistic regression analysis of odds of post-RT olfactory dysfunction in relation to olfactory-region dose, adjusted for relevant covariates measured using radiotherapy treatment plans at one timepoint

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Patients with histologically confirmed head and neck cancer scheduled for curative intensity modulated radiotherapy (IMRT) at Chang Gung Memorial Hospital
2. Provided written informed consent approved by the Chang Gung Medical Foundation IRB

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
63

Key exclusion criteria
1. Severe nasal septal deviation with hypertrophic turbinate
2. Chronic rhinosinusitis with or without nasal polyps
3. History of head trauma
4. Prior radiotherapy to the head and neck region
5. Baseline olfactory dysfunction defined as Taiwan Smell Identification Test (TWSIT) score <40

Date of first enrolment
12/01/2021

Date of final enrolment
17/11/2023

Locations

Countries of recruitment
Taiwan

Study participating centre
Chang Gung Memorial Hospital, Chiayi Branch
8, Sec. West Jiapu Road, Puzi City
Chiayi
Taiwan
61363

Sponsor information

Organisation
Chang Gung Memorial Hospital

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Research organisation

Funder Name
Chang Gung Medical Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Taiwan

Results and Publications

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. Individual participant data (IPD) will not be shared due to ethical and privacy restrictions. Only aggregated results will be reported in publications and presentations.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2025	04/02/2026	Yes	No