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# COSTAR - a multicentre randomised study of COchlear Sparing intensity modulated radiotherapy versus conventional Radiotherapy in patients with parotid tumours

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| **Submission date**<br>29/09/2006 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>29/09/2006 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>27/11/2025 | **Condition category**<br>Cancer | [_] Individual participant data |

**Plain English summary of protocol**
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-standard-radiotherapy-and-intensity-modulated-radiotherapy-for-people-with-parotid-gland-cancer

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT01216800

**Protocol serial number**
N0258171463

# Study information

**Scientific Title**
COSTAR - a multicentre randomised study of COchlear Sparing intensity modulated radiotherapy versus conventional Radiotherapy in patients with parotid tumours

**Acronym**
COSTAR

**Study objectives**
To determine in a randomised controlled trial the potential of intensity-modulated radiotherapy (IMRT) to reduce the incidence of sensori neural hearing loss in patients having radiotherapy to the parotid region.

**Ethics approval required**
Old ethics approval format

**Ethics approval(s)**
Royal Marsden Local Research Ethics Committee (UK), 07/03/2006, ref: 05/Q0801/183

**Study design**
Randomized controlled trial

**Primary study design**
Interventional

**Study type(s)**
Treatment

**Health condition(s) or problem(s) studied**
Cancer: Parotid

**Interventions**
Randomised study testing interventional (COchlear Sparing intensity modulated radiotherapy) vs standardised intervention, non-blinded (Phase III)

Added 27/11/2025:
Additional Data Linkage Information:
Participants from this trial will also be included in the INTERACT project which will link to their data held by NHS England. For more information, please see the INTERACT website: https://www.icr.ac.uk/interact.

**Intervention Type**
Other

**Primary outcome(s)**

Is the proportion of patients developing sensori-neural hearing loss at bone conduction assessed using audiograms at 4000 Hz, 1 year after treatment?

### Key secondary outcome(s)
Added 30 July 2008:
1. Auditory assessment at 6 and 12 months following radiotherapy and annually thereafter to 5 years
2. Vestibular assessment at baseline, at 6 and 12 months following radiotherapy and annually thereafter to 5 years
3. Quality of life at 6 and 12 months following radiotherapy and annually thereafter for 5 years
4. Local and regional tumour control (a quantitative description of sites of relapse will be performed)
5. Time to tumour progression and overall survival
6. Acute and late side effects of radiotherapy (NCI CTCAE scale v3.0, for acute and late side effects and LENT SOMA and late radiotherapy scoring systems)

### Completion date
01/08/2016

## Eligibility

### Key inclusion criteria
Prior to July 2008:
1. Histologically confirmed malignant tumours involving the parotid glands
2. Metastases from squamous cell carcinoma of the head and neck to the parotid gland
3. Benign tumours requiring post operative radiotherapy

Modified 30 July 2008:
1. Histologically confirmed malignant tumours of the parotid glands
2. High risk of radiation induced sensori-neural hearing loss with conventional radiotherapy due to the irradiation of the parotid bed to a dose equivalent of 60 Gy in 2 Gy fractions with photon beams, using the wedge pair technique
3. Radiotherapy as post-operative therapy (adjuvant irradiation)
4. WHO Performance Status 0-1
5. All patients must be suitable to attend regular follow-up and undergo audiograms and toxicity monitoring and be available for long term follow-up

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment

0

### Key exclusion criteria
Prior to July 2008:
1. Previous radiotherapy to the head and neck region
2. Previous malignancy except non-melanoma skin cancer
3. Pre-existing hearing loss or significant auditory pathology
4. Previous or concomitant illness, which in the investigators opinion would interfere with either completion of therapy or follow-up
5. Concomitant chemotherapy is not permitted

Modified 30 July 2008:
1. Previous radiotherapy to the head and neck region
2. Parotid tumours requiring primary radiation
3. Metastases from squamous cell carcinoma of the head and neck to the parotid gland
4. Benign tumours requiring post operative radiotherapy
5. Hearing loss >60 dB at time of study entry (the test is unreliable below this threshold)
6. Previous or concurrent illness, which in the investigators opinion would interfere with either completion of therapy or follow-up
7. Patients requiring concomitant chemotherapy

### Date of first enrolment
29/08/2008

### Date of final enrolment
31/01/2013

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
### Royal Marsden NHS Trust
-
London
England
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## Sponsor information

### Organisation
Institute of Cancer Research (UK)

**ROR**
https://ror.org/043jzw605

# Funder(s)

**Funder type**
Charity

**Funder Name**
Cancer Research UK

**Alternative Name(s)**
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Other non-profit organizations

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/11/2018 | 29/01/2019 | Yes | No |
| Plain English results | | 27/10/2021 | 27/10/2021 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |