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

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

Contact name
Dr Christopher Nutting

Contact details
Head of Head and Neck Unit
Royal Marsden NHS Trust
Fulham Road
Chelsea
London
United Kingdom
SW3 6JJ
+44 (0)20 7352 8171
Chris.Nutting@rmh.nhs.uk

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
SW3 6JJ

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results		27/10/2021	27/10/2021	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes