

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/10/2021	Condition category Cancer	<input type="checkbox"/> 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>

Study website

http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/9731_disease.shtml

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01216800

Secondary identifying numbers

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

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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)

Intervention Type

Other

Phase

Phase III

Primary outcome measure

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

Secondary outcome measures

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)

Overall study start date

01/07/2008

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

Age group

Adult

Sex

Both

Target number of participants

A total of 84 participants including 20 RMH participants.

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 >60dB 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

England

United Kingdom

Study participating centre

Royal Marsden NHS Trust
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation

Institute of Cancer Research (UK)

Sponsor details

123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type

Research organisation

Website

<http://www.icr.ac.uk/index.shtml>

ROR

<https://ror.org/043jzw605>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

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