ISRCTN48243537 https://doi.org/10.1186/ISRCTN48243537

A multi-centred randomised study of parotid sparing intensity modulated radiotherapy (IMRT) to reduce xerostomia and increase quality of life in head and neck cancer

Submission date
15/10/2002

Recruitment status
No longer recruiting

Registration date
15/10/2002

Overall study status
Completed

Last Edited
29/10/2021

Condition category
Cancer

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

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-a-new-method-of-radiotherapy-versus-standard-radiotherapy-for-head-and-neck-cancers

Study website
http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/2380_disease.shtml

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00081029

Secondary identifying numbers
Parotid Sparing IMRT

Study information

Scientific Title
A multi-centred randomised study of parotid sparing intensity modulated radiotherapy (IMRT) to reduce xerostomia and increase quality of life in head and neck cancer

Acronym
PARSPORT

Study objectives
Added 30 July 2008:
To determine in a randomised controlled trial the potential of intensity-modulated radiotherapy (IMRT) to reduce xerostomia and increase quality of life in head and neck cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 30 July 2008: South West MREC (03/6/79) - approved 11/11/2003.

Study design
Multi-centred randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Head and Neck cancer

Interventions
Patients are randomised to receive either conventional radiotherapy or parotid-sparing IMRT

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Added 30 July 2008:
The primary endpoint is the proportion of patients suffering xerostomia of grade 2 or more, assessed by the subjective measure on the LENT/SOMA late toxicity scale, one year after treatment.

Secondary outcome measures
Added 30 July 2008:
Secondary endpoints include:
1. Degree of xerostomia by quantitative measurements of stimulated and unstimulated salivary flow
2. Xerostomia related quality of life as measured by modified Xerostomia Questionnaire
3. Quality of life measured by the EORTC QLQ C30 v.3.0 and QLQ-H&N35 questionnaires
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 side effects and LENT SOMA and RTOG late radiotherapy scoring systems)

Overall study start date
01/01/2003

Completion date
31/01/2008

Eligibility

Key inclusion criteria
1. Histologically confirmed squamous cell or undifferentiated carcinoma of the head and neck
2. Tumour arising from the oro-pharynx requiring radical radiation of the primary tumour by parallel opposed lateral fields and bilateral cervical lymph node irradiation. High risk of radiation induced xerostomia with conventional radiotherapy due to irradiation of the majority of both parotid glands. Radiotherapy either as the primary treatment or post-operative (adjuvant irradiation). Neoadjuvant chemotherapy is permitted.
3. All patients must be suitable to attend regular follow-up and undergo QoL and salivary measurements. Stage T1-4, N1-3, M0 disease. Zubrod performance status 0-1.

Participant type(s)
Patient

Age group

Not Specified

Sex
Not Specified

Target number of participants
Added 30 July 2008: 84 (increased to 100 in March 2007). Recruitment completed January 2008, participants in follow up.

Total final enrolment
94

Key exclusion criteria
Added 30 July 2008:

1. Previous radiotherapy to the head and neck region
2. Previous malignancy except non-melanoma skin cancer
3. Pre-existing salivary gland pathology interfering with saliva production
4. Previous or concurrent illness which in the investigators opinion would interfere with either completion of therapy or follow-up
5. Patients with bilateral N3 nodal disease or huge primary tumour (exceeding 10cm in diameter)
6. Prophylactic use of amifostine or pilocarpine is not allowed
7. Concomitant chemotherapy is not permitted
8. Brachytherapy is not allowed as part of the treatment
9. Presence of contralateral lymphadenopathy adjacent to or involving contralateral parotid gland making parotid sparing impossible
10. Tumour of base of tongue where sparing of contralateral parapharingeal space is contraindicated

Date of first enrolment
01/01/2003

Date of final enrolment
31/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Head and Neck Unit
London
United Kingdom
SW3 6JJ

Sponsor information

Organisation
The Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Government

Website
http://www.icr.ac.uk

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Research organisation

Funder Name
Cancer Research UK (CRUK) (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?
Protocol article	protocol	01/10/2007		Yes	No
Other publications	pre-trial quality assurance processes	01/07/2009		Yes	No
Other publications	dosimetry audit	01/10/2009		Yes	No
Results article	parotid-sapring intensity results	01/02/2011		Yes	No
Plain English results		08/11/2011	29/10/2021	No	Yes