

# 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

<b>Submission date</b> 15/10/2002	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/10/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/10/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> 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](http://www.icr.ac.uk/research/research_sections/clinical_trials/clinical_trials_list/2380_disease.shtml)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Chris Nutting

### Contact details

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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 parapharyngeal 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?
<a href="#">Protocol article</a>	protocol	01/10/2007		Yes	No
<a href="#">Other publications</a>	pre-trial quality assurance processes	01/07/2009		Yes	No
<a href="#">Other publications</a>	dosimetry audit	01/10/2009		Yes	No
<a href="#">Results article</a>	parotid-sparing intensity results	01/02/2011		Yes	No
<a href="#">Plain English results</a>		08/11/2011	29/10/2021	No	Yes