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Recruitment of patients into head and neck clinical trials: acceptability of studies to patients from perspective of the research team

M.W. Ho [a,b,*], A.S. Pick [a], D.N. Sutton [a], K. Dyker [a,c], K. Cardale [a,c], K. Gilbert [d], J. Johnson [a], J. Quantrill [a], J.A. McCaul [d,e]

[a] *Head and Neck Research, Bradford Institute of Health Research, Bradford Teaching Hospitals NHS Foundation Trust, West Yorkshire, UK*
[b] *Oral and Maxillofacial Surgery, Leeds Dental Institute, University of Leeds, West Yorkshire LS2 9LU, UK*
[c] *Clinical Oncology, Leeds Teaching Hospitals NHS Trust, West Yorkshire, UK*
[d] *Clinical Trials, Northwick Park Hospital, North-West London, UK*
[e] *Oral and Maxillofacial/Head and Neck Surgery, NHS Greater Glasgow and Clyde, Scotland*

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Abstract

We reviewed longitudinal recruitment data to assess recruitment into head and neck cancer trials, and to identify factors that could influence this and affect their acceptability to patients. We retrieved data from the prospective computerised database (2009–2016) to measure acceptability to patients using the recruitment:screening ratio, and compared observational with interventional studies, single specialty (or site) with multispecialty (or site) studies, and "step-up" randomisation with "non-inferiority" randomisation designs. A total of 1283 patients were screened and 583 recruited. The recruitment:screening ratio for all National Institute for Health Research (NIHR) portfolio studies combined was 0.47 (486/1133). Studies that involved treatment by several specialties or at several sites had a significantly adverse impact on acceptability ($p = 0.01$). Recruitment into non-inferiority randomised controlled studies was lower than that into step-up randomised studies ($p = 0.06$). The complexity of a study's design did not compromise recruitment. Treatment across several specialties or several sites and perceived non-inferiority designs, reduced the acceptability of some trials.
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Keywords: Clinical trials; Head and Neck research; Trial recruitment; Acceptability clinical trials; Trial design

Introduction

Recruitment into head and neck clinical trials can be impeded by insufficient resources or logistical support, and poor acceptability to patients. Known barriers include patients' preferences for the type of treatment, aversion to randomisation, lack of equipoise amongst clinicians, and the complexity of the trial's design and the information provided.[1,2] The Specialty Clinical Studies Group at the National Cancer Research Institute has identified key areas of need for research or clinical trials, but the success of a study depends on the ability of the local head and neck trials team to recruit suitable patients, ideally within the projected trajectory of accrual. The head and neck team at the Bradford Institute for Health Research with the Bradford Teaching Hospitals head and neck mul-

* Corresponding author at: Maxillofacial Oncology, Leeds Dental Institute, LS2 9LU, UK.
E-mail address: michael.ho2@nhs.net (M.W. Ho).

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tidisciplinary team support the National Institute for Health Research (NIHR) portfolio of clinical trials.

The team supports a catchment of around 1.25 million residents of West Yorkshire, England, where about 150 patients each year are diagnosed with cancer of the head and neck. Recruitment into trials is reviewed annually (measured primarily by recruitment to projected targets) by the Yorkshire and Humber Clinical Research Network to secure continued funding of the head and neck trials team at the Bradford Institute for Health Research (0.1 whole-time equivalent head and neck surgeon and 1.5 whole-time equivalent clinical research nurses). Most studies on recruitment into clinical trials have been qualitative[1] or cross-sectional,[2] or consisted of the opinions of clinicians.[3,4]

We have therefore reviewed longitudinal recruitment data from a head and neck clinical trials team (since its inception) at a district teaching hospital to assess recruitment into head and neck clinical trials, and to identify factors that influence this and indicate their acceptability to patients.

Patients and methods

We accessed the computerised prospective database of the head and neck team at the Bradford Institute for Health Research to retrieve data on projected recruitment targets, the number of patients screened and recruited for each National Institute for Health Research (NIHR) portfolio observational trial, and every interventional study from 1 April 2009 to 30 May 2016. Patients who agreed to donate to the ethical tissue bank at the University of Bradford were excluded.

The acceptability of a study to patients (or relative success of recruitment into a clinical trial) is measured by the recruitment:screening ratio. The complexity of a trial or the acceptability of a NIHR portfolio trial to patients is reflected by the recruitment:projected recruitment target ratio. We compared observational with interventional, single specialty (or site) with multispecialty (or site), and step-up randomisation with non-inferiority, trials. The objective of non-inferiority trials is to compare a new treatment with an active treatment to show that it is not clinically worse with regards to a specified endpoint. It is assumed that the comparator treatment has a significant clinical effect compared with placebo. We used the Student's *t* test to compare the mean of the ratios (GraphPad QuickCalcs 7, GraphPad Software Inc). Probabilities of less than 0.05 were considered significant.

Results

Sixteen observational and interventional studies were opened to recruitment by the head and neck multidisciplinary team at Bradford Teaching Hospitals during the study period (Table 1). Overall, 1283 eligible patients were screened by the clinical trials team, and 583 recruited. The recruitment:screening ratio for all NIHR portfolio studies combined

Table 1
Brief description of observational and interventional trials opened to recruitment in Bradford Teaching Hospitals NHS Foundation Trust (1 April 2009–30 May 2016).

Trial	Subject	Current status	Design
Brush Biopsy	Dielectrophoretic analysis of brush biopsy specimen	Closed	Observational
DeteQT	Determination of QoL instrument most preferred by patients with thyroid cancer	Closed	Observational
Determin	Determination of quality of life instrument most preferred by head and neck patients	Closed	Observational
Head & Neck 5000	Clinical cohort study of 5000 patients with Head and Neck Cancer UK	Closed	Observational
PREDICTR	Molecular biomarkers: study in stratification of the management of individual patients with oropharyngeal cancer	Closed	Observational
PANDORA	Point-of-care Analysis by Non-invasive Dielectrophoresis for ORAl cancer diagnosis	Closed	Observational
TCUK	Thyroid cancer genetic investigation in the UK	Closed	Observational
EURECA	European research on electrochemotherapy in head and neck cancer	Closed	Interventional
DeESCALaTE	Determination of Epidermal growth factor receptor-inhibitor (cetuximab) versus Standard Chemotherapy (cisplatin) early And Late Toxicity Events in Human Papillomavirus-positive oropharyngeal squamous cell carcinoma	Open	Interventional
NIMRAD	A phase III trial to investigate the modified use of nimorazole hypoxia with intensity-modulated radiotherapy in head and neck cancer	Open	Interventional
LiDCO Rapid	LiDCo Rapid optimisation in major head & neck cancer surgery	Closed	Interventional
LIHNCS	The effectiveness of Lugol's Iodine to assist excision of marginal dysplasia at resection of oral and oropharyngeal squamous carcinoma	Closed	Interventional
TITAN	Trial of induction TPF therapy in advanced head & neck cancer	Closed	Interventional
PET Neck	A multicentre randomised phase III trial comparing PET-CT-guided watch-and-wait policy compared with planned neck dissection for the management of locally advanced (N2/N3) nodal metastases in patients with head and neck squamous cancer	Closed	Interventional
LEONIDAS 2	Long-term Evaluation of the effectiveness Of a Novel Intraoral electrostimulator for the treatment of raDiotherapy-ASsociated dry mouth	Closed	Interventional
HOPON	Hyperbaric oxygen in prevention of mandibular osteonecrosis	Open	Interventional
DAHANCA 21	Hyperbaric oxygen treatment of mandibular osteonecrosis	Open	Interventional

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