

R36 Workshop on the design and analysis of clinical trials in Head and Neck cancer

Investigators

Lead applicants:

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Co-applicants:

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Original Aim

The original aim of this project was to develop and host a two-day education workshop with the following objectives:

1. To provide training and resources in clinical trials methodology for trainees wishing to specialise in head and neck cancer.
2. To present current challenges in head and neck cancer trials through a series of presentations from head and neck cancer trialists and methodologists to cover topics such as recruitment, equipoise, outcome selection, patient preference designs, issues for surgical trials, and issues for multimodality trials.
3. To provide a forum for open discussion, and networking between trainees, experienced head and neck cancer clinicians, and trials methodologists.
4. To provide a forum for discussion of ideas for future trials in head and neck cancer, with a particular focus on identifying and prioritising the methodological issues.
5. To encourage further collaboration between the head and neck cancer clinical community with the trials methodology research community.

What was achieved

The 2-day workshop was developed as planned and included contributions from trial methodologists and clinicians (Program in Appendix). Methodological issues were discussed and a pre-workshop survey used to capture current thinking and identify particular issues. There were 20 head and neck/surgical trainee delegates from across the UK. By the end of the workshop trainees had worked up their own trial ideas which they were asked to present to a panel for feedback. Feedback received about the workshop has been very positive

Dates of the workshop

9-10th December 2013

Outputs since the workshop:

- (i) One of the trial ideas developed at the workshop is to be discussed with the NCRI H&N CSG at the next meeting, and a second trial idea has been through approval by the group and has been submitted as a grant application to the NIHR HTA.
- (ii) A portal has been established to provide a forum for discussion about trials and methodological issues for this community of trainees.
- (iii) A publication summarising the workshop being prepared for submission to a head and neck journal

Impact of the workshop

- (i) Direct impact on developing two trials
- (ii) The workshop has been cited in a submission to an international H&N surgery journal, currently under review, as an example of best practice in developing surgical trial methodology and training

- (iii) The model of engaging senior trainees in cancer surgery to highlight trials issues and in particular methodological aspects of surgical trials has come to the notice of the National Cancer Research Institute and Network - This has led to the creation of a new associate directorship post with responsibility for surgical oncology, and also several workstreams. One of the projects is to model surgical trials workshops on this HTMR supported H&N Liverpool event, that will be specialty specific and based around the cancer site CSG groupings in order to drive this agenda forwards. Another issue is that several aspects of surgical trial methodology are seen to be generic across the cancer sites, and these will be tackled by a new clinical studies group to address such issues as QA in surgical trials and accreditation, early phase trials for new operations and devices, minimal access surgery etc.

Next steps

- (i) Seek further funding to run the workshop again to other cancer specialities
- (ii) Write up a short paper summarising the methodology research priorities identified during the workshop

Appendix: Workshop programme

Clinical Trials in Head and Neck Cancer

Monday 9th December 2013

An introduction to clinical trials

10.00	Registration and coffee	
10.30	Welcome	Richard Shaw
10.35	MRC Hubs for trials methodology research	Jane Blazeby Catrin Tudur Smith
10.45	What do you need to do to design a trial? Part 1 Define the question (PICO) Trial Design Considering Bias Group work – designing your own trial	Ashley Jones Beth Conroy Jelena Savovic Delegates
13.00	Lunch	
13.45	What do you need to do to design a trial? Part 2 Pragmatic versus explanatory trials How big? How feasible?	Jane Blazeby Catrin Tudur Smith Helen Hickey
15.00	Critical appraisal of published clinical trials Group work – critical appraisal of head and neck cancer trials	Catrin Tudur Smith Richard Shaw Delegates
16.00	Tea/Coffee	
16.15	Clinical trials units	Charlotte Rawcliffe
17.00	Trial ideas Group work – finalise trial idea to present to panel on day 2	Delegates
18.00	Close	
19.00	Dinner	

Tuesday 10th December 2013

Methodological Challenges in Head and Neck Cancer Trials

09.00	Coffee / arrival	
09.25	Introduction to Day 2	Richard Shaw
09.30	Core outcomes in H&N trials	Aoife Waters
09.50	QOL as an outcome measure in H&N trials	Simon Rogers
10.10	Early phase trials for H&N surgeons	Terry Jones
10.30	Coffee	
10.50	Biomarker led H&N trials (especially HPV)	Richard Shaw
11.10	Surgery as part of multidisciplinary trials approach	Mererid Evans
11.40	Introducing surgical innovation	James McCaul
12.00	Lunch	
12.40	Patient treatment preferences at trial recruitment	Nicola Mills
13.00	Optimising recruitment to phase III trials	James McCaul
13.20	H&N trials – how to get funded	Vinidh Paleri
13.45	H&N trial methodology (with coffee) Trial presentations (5 mins each) – with panel feedback	Delegates
14.30	What are the methodological challenges in H&N cancer trials?	Group Discussion
15.00	Closing comments & feedback	Richard Shaw