PET-NECK: Setting Up A Collaborative Clinical Trial In A Rare Disease Site

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Background

•PET-NECK is a national, multi-centre, randomized phase III trial comparing PET-CT guided 'watch and wait' with planned neck dissection for the management of locally advanced (N2/N3) nodal metastases in patients with head and neck squamous cancer (Figure 1).

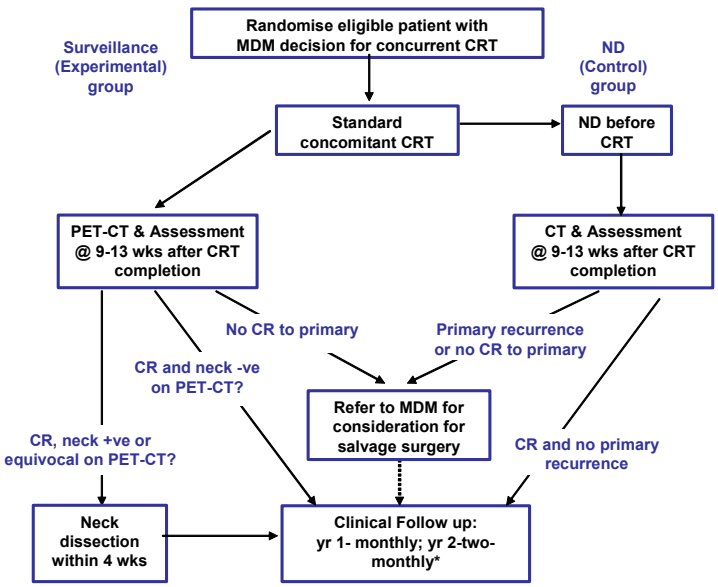
•7,000 new Head & Neck Cancers (HNC) per year in the UK of which we estimate 30% will eventually be eligible for the trial.

•HNC is treated at specialist centres of which there are around 20 in the UK.

•The UK has invested in the establishment of a National Cancer Research Network who can provide support for National Cancer Research Network (NCRN) trials.

•PET-NECK is currently the only phase III trial in the NCRN trials portfolio and is compatible with commercial drug trials

Fig.1: PET-NECK Trial Design



CRT: radical concurrent chemoradiotherapy
CR: complete response of primary site on post treatment assessment
ND: neck dissection (either modified or selective)
PET-CT: Positron Emission Tomography – Computerised tomography scan
Assessment - CT and/or MRI + Examination under anaesthetic (EUA) post completion of CRT

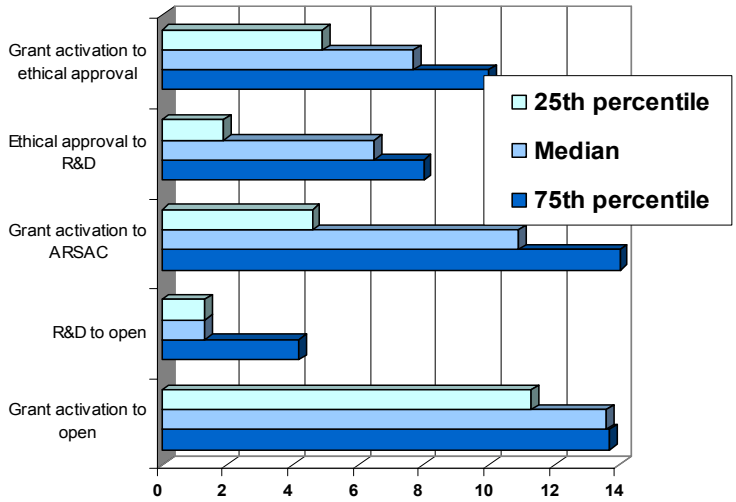
Primary endpoints:
Overall Survival

Secondary endpoints:
- •Disease specific survival
- •Local control in neck
- •Surgical complication rates
- •Quality of life
- •Healthcare economics

Milestones

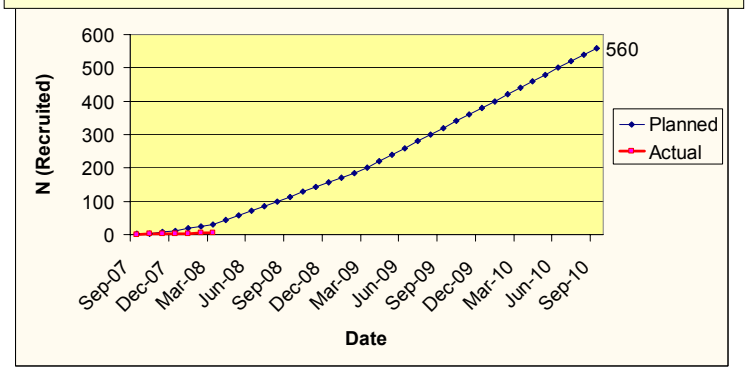
- •Funding awarded: 1st Apr 2007
- •Approval in place at principal site: 1st June 2007
- •Co-ordinator starts in post: 30th Aug 2007
- •1st patient entered: 2nd Oct 2007
- •Anticipated recruitment of 560 patients: Sept 2010

Fig.2: Time to approvals



Key: ARSAC=Administration of Radioactive Substances Advisory Committee
R&D=Research and Development

Fig.3: Overall recruitment



•Time to approval was slow for the first centres since they all had to wait for initial ethics, R&D and ARSAC approval; subsequent centres have reduced approval time (Figure 2).

•The trial involves many disciplines (e.g. surgery, medical oncology, clinical oncology, radiology, pathology) extending the local R&D approval time.

• PET-CT scanning is a 'new' technology with the distribution of scanners increasing rapidly. There remains a need for training and Quality Assurance.

•Recruitment will be on track at the end of the year; 29 sites (Figure 3).

Conclusions

•Establishing a clinical trial in a rare cancer disease site with little pre-existing infrastructure and involving new technology is challenging.

•Recruitment to this trial has started due to the persistence of the Trial Centre, dedication of the Trials Team and the UK prioritisation of Clinical Trials in the National Health Service.

•This trial serves an under represented group of people with cancer and it remains imperative to continue to answer this important question

Contact

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•We gratefully acknowledge the HTA for funding PET-NECK.

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