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

Fig.2: Time to approvals

Fig.3: Overall recruitment

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

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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