Aintree University Hospital NHS
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MERSEY HEAD & NECK ONCOLOGY RESEARCH GROUP

HEAD & NECK ONCOLOGY CLINICAL TRIALS

Welcome to the Spring 2015 edition of the Aintree 'Head and Neck Oncology Clinical Trials' Newsletter.
The rationale for the newsletter is to keep all staff associated with the 'Merseyside Regional Head and Neck Cancer Centre' up to date with studies currently open and recruiting at Aintree as well as news on possible future studies, studies that have closed and any other relevant information relating to our activity.

Research Studies currently open and recruiting at Aintree:

Randomised Controlled Trials:

HOPON – 66 patients recruited
SEND – 27 patients recruited
TRISMUS – 21 patients recruited
DAHANCA21 – 3 patients recruited

Cohort Studies:

Head & Neck 5000 – 600 patients recruited
AWARE – 32 patients recruited

Tissue Banking:

325 Patients donated to the Liverpool Tissue Bank
102 Patients donated to the Molecular Determinants of Head and Neck Cancer Study.
For more information on the specific nature of each of these studies click on the Excel Logo.

Trial info 1.4.xlsx

Head and Neck 5000 closes to recruitment

Newsletter No. 11
February 2015

headandneck 5000

Our final recruitment total is 5511 participants

A huge thank you to everyone for helping us to get this far

Congratulations to Aintree who were our highest recruiting site with 600 participants. Shirley, Paul, Linda and their team have been working on the study since 2011

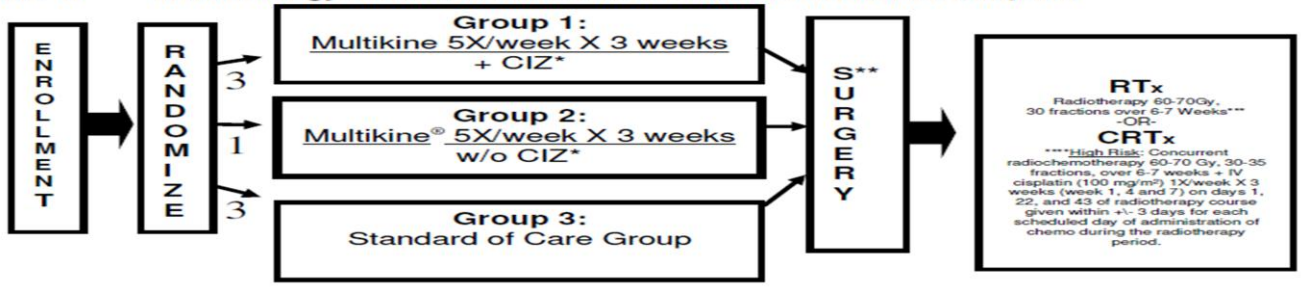
Multikine Study gets Aintree R&D approval – patient recruitment imminent

MULTIKINE STUDY

This study will test Leukocyte Interleukin, Injection [Multikine®] (study drug), an experimental drug being developed by CEL-SCI.
The main purpose of this study is to determine whether Leukocyte Interleukin Injection (LI) in combination with CIZ regime (Cyclophosphamide, Indomethacin and nutritional supplementation with multivitamins plus zinc) - given prior to standard of care therapy (SOC), will increase the overall survival of 'Oral Cavity SCC' patients beyond that currently achieved with SOC alone. The current SOC for 'Oral Cavity SCC' patients is surgery plus radiotherapy or surgery followed by radiotherapy plus concurrent chemotherapy with Cisplatin.
The safety of LI and the side effects that could occur from LI or the LI +CIZ treatment regimen will also be evaluated. The ability of LI and the LI +CIZ treatment regimen to stimulate the immune system will also be measured.
Biopsies will also be taken and examined by scientists to see if any tumour markers can be recognized or anti-tumour effects can be seen. Biopsy samples will be taken before treatment and during surgery.

Study Group – Tongue, Floor of Mouth, Cheek, Soft Palate
T1 N1-2 M0, T2 N1-2 M0, T3 N0-2 M0, T4 N0-2 M0

Table 1. Methodology: Randomization and Treatment of Enrolled Subjects



* CIZ: Cyclophosphamide 300 mg/m2 (x1,IV bolus, Day -3); Indomethacin 25mg tid, po (Day 1 to approximately 24 hrs prior to surgery) + Zinc (as Multivitamin) po id (daily, from Day 1 to approximately 24 hours prior to surgery).
** Surgery: complete surgical resection of primary tumor and any positive lymph nodes.
*** Radiotherapy is to be given per protocol at a total of ≥ 60 Gy to ≤70 Gy (in 30-35 fractions over a 6-7 week period).
**** High risk subjects are defined as those with: positive surgical margins, 2 or more clinically positive nodes, or extracapsular nodal spread (any or all of the above).

Getting it right for every patient every time

CANCER RESEARCH UK

EPRC

Liverpool Cancer Trials Unit

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New study (Pathos) in set up!

Pathos

WCTU
WALES CANCER TRIALS UNIT
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The **Pathos** study will recruit approximately 242 patients from around the UK over 3 years. The aim is to tailor treatment for patients with HPV-positive Oropharyngeal cancer to reduce side-effects, particularly swallowing problems, which have the major impact on quality of life.
For patients enrolled into PATHOS, it will have been decided by local teams that they should undergo surgery to remove the primary tumour in the tonsil, throat or tongue using a laser or robot. A neck dissection will also be carried out to remove the lymph glands in the neck which may also contain cancerous cells. After surgery, the cancer that has been removed will be examined by a pathologist for features that can help predict whether further treatment in the form of radiotherapy and/or chemotherapy is recommended.

(PATHOS group A) will be the patients who do not require any further treatment after surgery.

(PATHOS group B) is patients for whom radiotherapy alone is recommended. They will be randomly allocated to receive either standard dose post-operative radiotherapy (60 Gray in 30 treatments over 6 weeks) or lower dose radiotherapy (50 Gray in 25 treatments over 5 weeks).

(PATHOS group C) will be allocated to receive either radiotherapy with chemotherapy (Cisplatin) or radiotherapy alone at the same dose (60 Gray in 30 treatments over 6 weeks). The patient will be allocated to either group B or C depending on the results received from the pathologist.
The aim is to see if long term toxicity, particularly swallowing problems, can be reduced in patients receiving either lower dose radiotherapy (group B) or no chemotherapy (group C), without affecting the chance of cure. If the study recruits well, it will continue to recruit >800 patients to prove that cure rates are maintained.

Pathos – Broad Inclusion criteria:

*T1-T3, N0-N2b Histologically confirmed diagnosis of Oropharyngeal SCC.
*HPV positive on central testing.
*Local MDT decision to treat with primary transoral resection and neck dissection
*Patient fit for surgery and adjuvant treatment.

Information regarding open trials/ studies at Aintree is available as a pocket sized laminate on request from the Head & Neck Clinical Trials team.

H&N MDT NIHR Portfolio / Clinical Trials Group Meeting.

Portfolio recruitment is a core activity of the regional head and neck cancer service, therefore trial adoption choices, smooth processes and recruitment issues will be discussed by an inclusive group meeting prior to the **fifth week MDT. (Next meeting 29th April 2015)**
The group includes representatives from Clinical Oncology, Medical Oncology, Surgical staff, Multi-Disciplinary Chair, Research Nurses, Pathology and Radiology staff, R&D Managers and any other clinicians with an interest who wish to attend.

If you require information about any of the ongoing Head & Neck Oncology studies or implementation of any new studies, please contact:
Shirley Pringle or Paul Banks Head & Neck Oncology Research Practitioners
or Linda Kearns, Data Manager on:
TEL: 0151 529 5873

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