

ARDEN CANCER RESEARCH NETWORK

Spring 2007 Newsletter

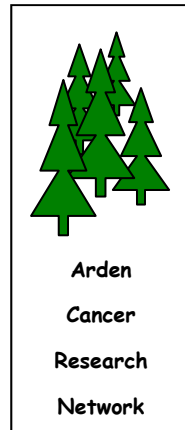
The Arden Research Network has had another very successful year. We have recruited 618 cases putting us 8th overall nationally in terms of percentage recruitment for our population size. Given the difficulties we have experienced with the move to the new hospital and limited chemotherapy capacity across the network (exacerbated by the introduction of the adjuvant Herceptin) this is a very commendable performance. The next year should see some very significant research network developments. I am very grateful to everybody for their continued enthusiasm and support for clinical trials.

The UHCW is looking to increase chemotherapy capacity within the Arden Cancer Centre and to expand an academic base on the 3rd floor of the main hospital. It is anticipated that this will provide 6 chemotherapy beds and associated accommodation for the new academic Professor along with a new base for the NCRN research team. If we are to proceed to provide a comprehensive portfolio of studies and offer patients an equitable service then these developments are essential.

We are fortunate to have a constant 'pile' of studies waiting to be activated, initiated by clinicians across the network. We are keen that the clinicians continue to drive the expansion of the trials portfolio. Please contact us at the trials centre, we would be delighted to hear from you.

Our network really has been very successful particularly for its size. This has been due to the enormous collaboration of staff from all parts of the oncology service. I hope with these changes coming through in the near future that we will be able to improve on our current excellent position and develop into an even more effective and productive research group.

Dr R.J.Grieve
Clinical Lead



Network success stories	2
Network recruitment	3
Studies in the spotlight	5
Studies recently activated	6
Studies coming soon	6
Studies closed	7
Network developments	8

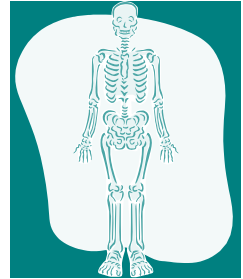
"We, the Arden Cancer Research Network team, are committed to the provision of an equitable and comprehensive clinical trials service for individuals affected by cancer.

We offer individuals and their families the opportunity to participate in research with the ultimate aim of improving cancer care for the future."

Network Success Stories

ZICE

A randomised phase III , open label , multicentre, parallel group clinical trial to evaluate and compare the efficacy, safety profile and tolerability of oral Ibandronate versus intravenous Zoledronate in the treatment of breast cancer patients with bone metastases.

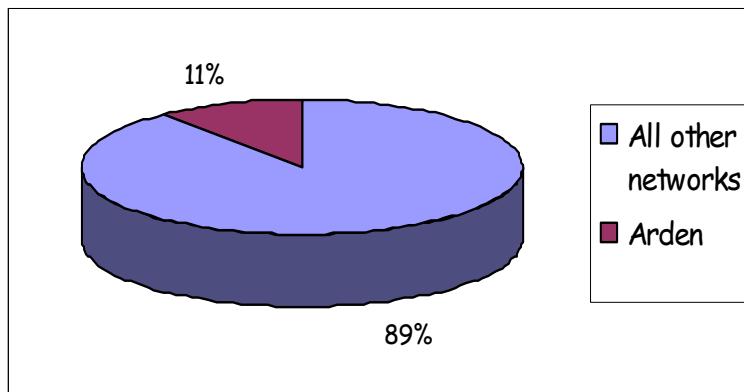


University Hospital moves into third place in ZICE trial recruitment.

The ZICE trial turned one year old on the 4th January 2007. The first patient was recruited at the Chief Investigators site of Velindre Hospital on 13th January 2006.

There are now a total of 140 patients recruited into this trial and University Hospital has just moved into third place on the top recruiting centres table with a total of 14 patients.

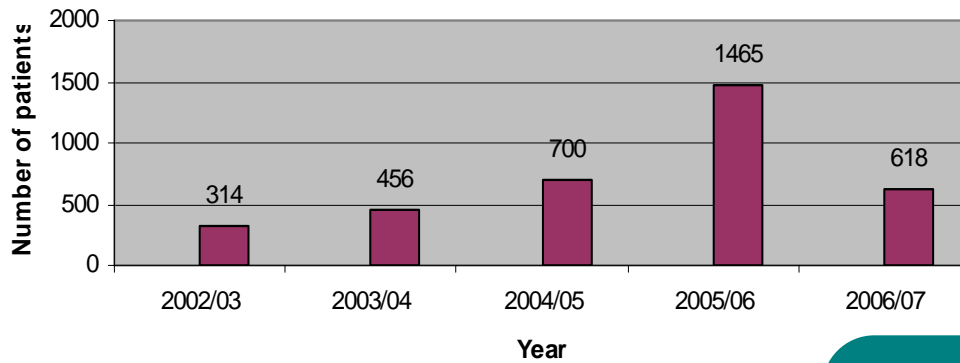
The total number of patients recruited for the Arden Cancer Research Network is 17 which is an excellent result as recruitment in this network started 6 months later in September 2006.



Network Recruitment 2002 to 2007

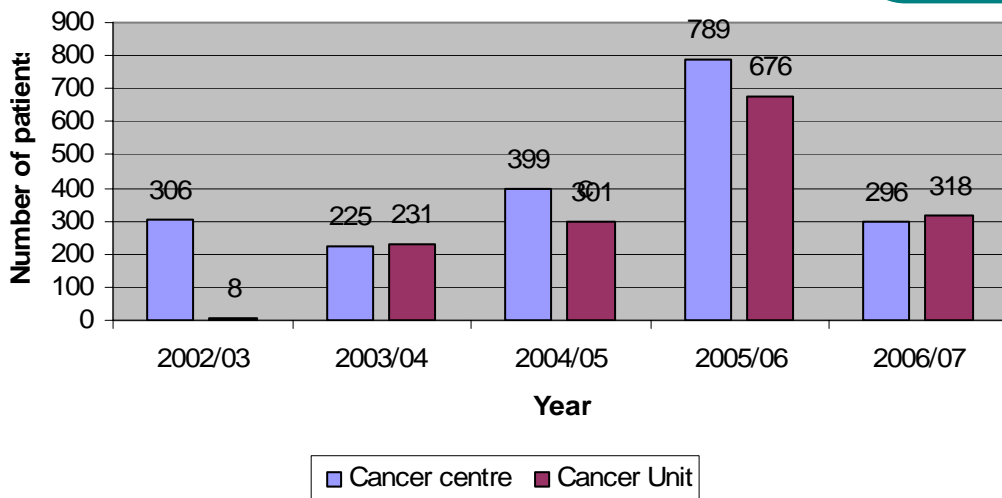
Our overall recruitment has dropped from last year, in particular, our recruitment to randomised controlled trials has dropped significantly. There are a number of reasons for this, firstly the effect of limited chemotherapy capacity coupled with the availability of studies on the NCRN portfolio and increasingly complex trial start up procedures. The Network is making every effort to address these issues. Our overall recruitment for 2006/7 was 15.3% still above the national average of 12%. Broken down into randomised (RCT) and non randomised, this is 3.3% and 12% respectively.

Annual recruitment for Network



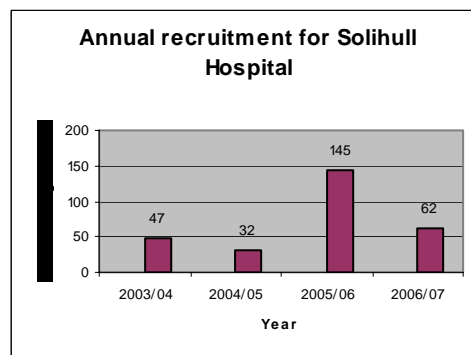
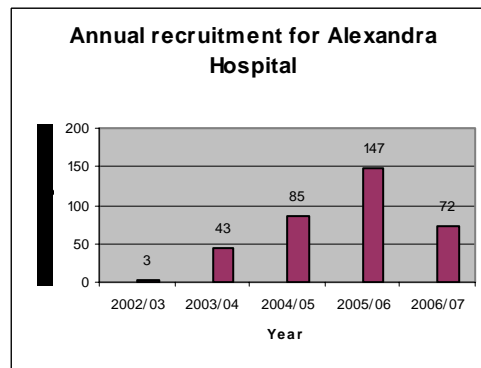
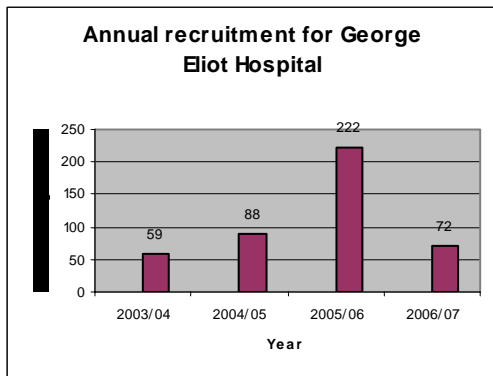
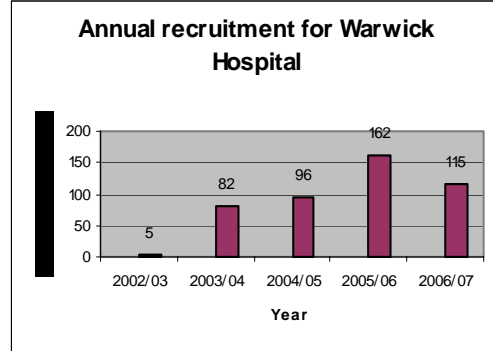
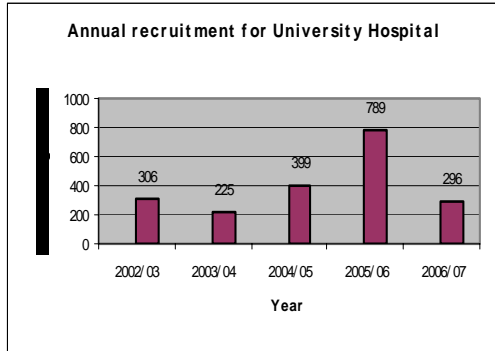
A total of 618 people were recruited to trials in 2006/07

Annual recruitment Centre and Units



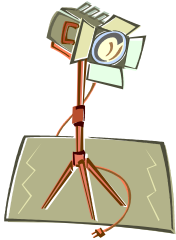
The recruitment figures are shown on an yearly basis from the 1st April to the 31st March.

Recruitment by hospital 2002 to 2007



Solihull Hospital recruits to breast trials only.

Studies in the spotlight



In this newsletter the two studies in the spotlight are **TOPICAL** and **RIB**.

If you have any eligible patients please contact the lung clinical trial nurses

Linda Wimbush (UHCW)

Elaine Simmons (Warwick Hospital)

June Jones (George Eliot Hospital)

On extension

27151

Direct line 024 7696 7151

TOPICAL

Tarceva or placebo in clinically advanced non small cell lung cancer (NSCLC) for patients unsuitable for chemotherapy

- ◆ Histologically or cytologically confirmed NSCLC
- ◆ Advanced disease stage IIIb or IV
- ◆ Chemotherapy naïve patients
- ◆ No prior palliative XRT (except to bone mets)
- ◆ No brain mets
- ◆ Able to take oral medication
- ◆ Not taking Cox II inhibitors
- ◆ CT scan within 4 weeks of randomisation

RIB

A randomised trial of single dose radiotherapy, compared to a single IV infusion of Ibandronate for the localised treatment of metastatic bone pain

- ◆ Histological confirmation of primary breast, lung or prostate cancer
- ◆ Confirmed bone mets (can be multiple) for which XRT is indicated
- ◆ Patient able to identify one area of localised bone pain

If complete or partial response-No further treatment required

If no change or relapse -Can crossover to alternative treatment

Studies Recently Activated

REACT - A phase III multicentre double blind randomised trial of celecoxib versus placebo in primary breast cancer patients.

BISMARCK - Cost-effective use of bisphosphonates in metastatic bone disease - a comparison of bone marker directed zoledronic acid therapy to a standard schedule.

SUPREMO - Selective use of post mastectomy radiotherapy after mastectomy.

CHRONICLE—Chemotherapy or no chemotherapy in clear margins after neoadjuvant chemoradiation in locally advanced rectal cancer A randomised phase III trial of control vs capecitabine plus oxaliplatin.

OE05— A randomised controlled trial comparing standard chemotherapy followed by resection versus ECX chemotherapy followed by resection in patients with resectable adenocarcinoma of the oesophagus.

QUARTZ - A phase III multicentre randomised controlled trial to assess whether optimal supportive care (including dexamethasone) alone is as effective as optimal supportive care (including dexamethasone) and whole brain radiotherapy (WBRT) in the treatment of patients with inoperable brain metastases from non-small cell lung cancer (NSCLC).

PATCH— Prostate Adenocarcinoma: TransCutaneous Hormones. A randomised-controlled trial of transcutaneous oestrogen patches versus LHRH analogues in prostate cancer.

DA v DAS in prostate cancer— A Randomised Phase III Trial of Dexamethasone and Aspirin (DA) Versus Dexamethasone, Diethylstilbestrol and Aspirin (DAS) in Locally Advanced or Metastatic Cancer of the Prostate.

UK Genetics of Testicular Cancer Study - Identification of testicular germ cell tumour susceptibility genes.

Studies Coming Soon

ICON7 - A randomised, two-arm, multicentre Gynaecologic Cancer InterGroup trial of adding bevacizumab to standard chemotherapy (carboplatin and paclitaxel) in patients with epithelial ovarian cancer.

FRAGMATIC - A randomised phase III clinical trial investigating the effect of FRAGMin Added to standard Therapy In patients with lung Cancer.

SOCCAR - Sequential or Concurrent Chemotherapy and radiotherapy in NSCLC.

CHHIP - Conventional or Hypofractionated High Dose Intensity Modulated Radiotherapy for Prostate Cancer.

PICCOLO - A randomised clinical trial of treatment for fluorouracil-resistant advanced colorectal cancer comparing standard single-agent irinotecan versus irinotecan plus panitumumab and versus irinotecan plus ciclosporin.

ASPECT (at Warwick Hospital) - A Phase III, randomised study of aspirin and esomeprazole chemoprevention in Barrett's Metaplasia.

TACT2 - Trial of Accelerated Adjuvant Chemotherapy With Capecitabine in Early Breast Cancer.

Persephone - Duration of Trastuzumab with chemotherapy in women with early breast cancer - six months versus twelve months.

Studies Closed

COMICE—Multi-centre randomised controlled trial examining the cost-effectiveness of contrast-enhanced high field magnetic resonance imaging in women scheduled for wide local excision.

RIB (in Solihull only) A randomised trial of single dose radiotherapy, compared to a single IV infusion of Ibandronate for the localised treatment of metastatic bone pain.

ODMIT C—A multicentre, prospective, randomised study to the value of a single dose of intravesical mitomycin in preventing the development of bladder tumours following nephroureterectomy for transitional cell carcinoma of the upper urinary tract.

Cancer Research Network Measures

The final draft of the Cancer Research Network Measures has been published and can be found in the cancer section on the DOH website www.dh.gov.uk or the CQuINS website www.cquins.nhs.uk. It is the intention to add the Cancer Research Network Measures to the Manual of Cancer Services 2004.

The National Cancer Research Network Co-ordinating Centre (NCRNCC) sets procedures for inclusion of studies to each Cancer Research Network's research portfolio, and sets targets for the numbers recruited into clinical trials and other well designed studies. The measures in the Manual for Cancer Services concentrate on reviewing the interaction between a Cancer Research Network and its local cancer network.

As we are expecting to be peer reviewed against these measures in March 2008, we need to start thinking about how we can comply with them. The responsibility for review purposes for the functions of the Research Network lies with the Research Clinical Lead - Bob Grieve. Measures that are most pertinent to us are those that cover the functions of the Network Site Specific Group and the local MDTs.

In the first instance we need to review the previously agreed list of approved clinical trials. Once this has been done, each MDT (having an identified person to lead research) needs to provide a written response to this list agreeing to enter patients or stating reasons why it will not be able to.

Donna and Judith will be facilitating compliance with the measures and will be liaising with the NSSG/ MDTs and Research Lead over the next few months.

Network Developments

Negotiations are now reaching their final stages of appointing a Professor of Oncology to complement the existing work within the NCRN and also most particularly Professor Janet Dunn who has been appointed Professor of Clinical Trials at Warwick University. The University has been extremely generous in supporting this initiative and we hope that within the next few months this post will be appointed to with the very necessary supporting infrastructure.

Over the last few months there have been several changes to the Clinical Trials Team with new positions being created and other posts being replaced:

- The trials team now employs a clinical trials nurse - Rachel Baseley, who supports the administration of trial treatments to patients which are in excess of the standard treatment and cannot be accommodated within the Arden Cancer Centre. Rachel also assists with patient follow-up which is a part of many of the trial protocols.
- Marianne Gakhal has joined the team as a clinical trials pharmacy technician; she supports the team for three mornings a week with the pharmacy requirements of trials.
- Sue Elwell has joined the team as one of our new Clinical Trials Administrator; she will shortly be joined by two other members of staff bringing the clinical Trials Administrator post to full complement (1.5 WTE). Once we are at full strength again, the process of taking trials though all the regulatory requirements will speed up.

The team is pursuing the appointment of a pathology technician to deal with the pathology requirements of many of the trial protocols.

