Clinical trials update
Nicola Naraine
Haematology Research Nurse
The Royal Bournemouth Hospital

Research is important to patients
• 97% of the public believe it’s important for the NHS to support research into new treatments
• 93% want their local NHS to be encouraged or required to support research
• 72% would like to be offered opportunities to be involved in trials of new medicines or treatments, if they suffered from a health condition that affects their day-to-day life
  - Association of Medical Research Charities
  - Ipsos Mori poll. Published June 2011.

Research is essential to deliver excellent patient care in the NHS
• To deliver the best possible treatments for patients we need evidence on “what works”
• Political duty and commitment to clinical research
• NHS Constitution: clinical research is “core business” for the NHS
• Opportunity to embed research as front line activity

NIHR Clinical Research Network
• NIHR Mission: Supporting research to make patients, and the NHS better
• NIHR Vision: For patients and carers, healthcare professionals and NHS decision makers across the country to embrace research as a standard component of patient care, and for the NIHR CRN to be valued by all its stakeholders as an integral part of successful research delivery
  - www.nihr.ac.uk

Why clinical trials are needed
In cancer, clinical trials are most commonly used to:
• try out new forms of treatment such as surgery, radiotherapy or chemotherapy
• control symptoms, such as pain and sickness
• test the effectiveness of psychological therapy

The treatment being tested may be aimed at:
• improving the number of people cured - (where the cancer doesn’t come back)
• improving survival - (how long people live before the cancer comes back)
• relieving symptoms of the cancer
• relieving the side effects of treatment
• improving the quality of life or sense of well-being for people with cancer
New cancer drugs tested in phase 1, 2 and 3 trials.

**PHASE 1 TRIALS:**
- how much of the treatment can be given without causing serious side effects
- if the drug has an effect on the body
- what side effects it causes
- whether the drug has any effect on the cancer

**PHASE 2 TRIALS:**
- if the treatment works well enough to be tested in a larger, phase 3 trial
- which types of cancer it might be best used to treat
- more about the side effects
- more about the best dose to use

**PHASE 3 TRIALS:**
- how long patients stay free of cancer (known as disease-free survival)
- the number of people who are alive, with or without signs of cancer (known as overall survival)
- whether the cancer grows more slowly
- how the treatment affects patients’ quality of life

- Specifying paraprotein levels in blood and urine
- Identifying the secondary effects of myeloma especially in relation to bone and the kidneys
- Recognising the crucial importance of a high fluid intake to help prevent kidney damage
- The introduction of high-dose therapy and autologous stem cell transplantation to the treatment options for myeloma
- The introduction of thalidomide as part of an initial combination treatment option for patients
- Discovering that inclusion of the bisphosphonate Zometa® (zoledronic acid) to a standard initial treatment combination offers additional anti-myeloma effects and improves survival in newly diagnosed patients over and above its effects against myeloma bone disease

**Myeloma XI Trial. Version 6.0**

- Randomised comparisons, in myeloma patients of all ages, of thalidomide, lenalidomide, carfilzomib and bortezomib induction combinations, and of lenalidomide and combination lenalidomide vorinostat as maintenance

**Purpose of Myeloma XI Study**

- to compare thalidomide, Revlimid, Carfilzomib and Velcade combinations in newly diagnosed patients in an intensive and non-intensive setting.
- to determine whether Revlimid or thalidomide-containing treatment is best
- then to identify which sequence of treatment combinations potentially offers improved benefit to myeloma patients
Myeloma XI to answer key questions

- Is a Revlimid-containing initial treatment more effective and does it have fewer side-effects than a thalidomide-containing one?
- Does Carfilzomib in combination with cyclo/RevDex have an effect on short term and long term response?
- Does Velcade-containing consolidation treatment help those who have not responded well to the initial treatment?
- Does maintenance treatment with Revlimid alone, or in combination with vorinostat, increase the time the myeloma remains stable after initial treatment, and prolong survival?

Randomisation to first treatment (known as 'induction treatment')
- Cyclophosphamide
- Thalidomide
- Dexamethasone
- Revlimid (lenalidomide)

Assess how well your treatment has worked
- If your myeloma has not responded or has got worse
- If your myeloma has responded very well
- If your myeloma has responded partly

Myeloma XI Intensive Arm
- Velcade (bortezomib)
- Cyclophosphamide
- Dexamethasone
- No consolidation chemotherapy

Myeloma XI Non-intensive Arm
- Velcade (bortezomib)
- Cyclophosphamide
- Dexamethasone
- Response Assessment

Randomisation to next treatment (consolidation chemotherapy)
- Revlimid (lenalidomide)

Randomisation to maintenance treatment
- Stem cell collection and high dose melphalan treatment and stem cell transplant

Other Trials
Visit the Myeloma UK website for further information:
www.myeloma.org.uk/information/clinical-trials-and-novel-drugs/