Neptune Trail Presentation – A Lay perspective by Hilary Blackburn

IPCV members who attended the March study day were interested and pleased to hear a short presentation from Dr Jenny Glendenning (researcher) Kings and her team on an innovative new clinical trial design for Triple negative breast cancer patients. . Characteristics of these types of cancer are that they are often "aggressive" high grade tumours and due to their "lack" of tumour receptiveness, there are currently, no standard maintenance protocols.

This trial summary has increased significance for me as I was diagnosed with this particular tumour type in 2002 as a relatively young woman of 32 years at the time. Clinical trials for this particular community of breast cancer patients have been relatively unexplored. Acknowledging the recent work of Andy Tutt and Alan Ashworth in 2010 at the Breakthrough Research Centre, there has still been little research or consensus to date as to the most effective management of these cancers. Despite my active lay interest in research, the lack of obvious progress with clinical trials in this area, has been striking and, at times, disconcerting.

My Short Trial Summary

Current recommended standard treatment involves the use of chemotherapy, surgery and radiotherapy and relatively recently, the use of taxanes is now accepted first line treatment. Despite some improved clinical insight, it remains a challenge to improve outcomes for this group of patients and to find effective pathways to target tumours which lack receptor status. For obvious reasons, this eliminates the opportunity for a course of oestrogen modifiers such a Tamoxifen or Arimidex as a protective follow up to treatment. There is currently no agreed targeted follow up treatment for what is recognised as a particularly aggressive tumour type.

Many TNBC cancers appear to have a similarly impaired DNA damage repair to the genetic breast cancers.This trial is focused on targeting this Achilles heel" which exists in both tumour types and may benefit from similar approaches This opportunity arises as a result of the use of a group of drugs known as PARP inhibitors. Work in the genetic laboratory has already exposed an opportunity to use these drugs to target "impaired" DNA whilst leaving normal tissue unharmed. In this trail, the specific drug for trial use in this way is 'iniparib'

Current and "pending" trails

Breakthrough Breast Cancer held their first UK conference in March 2011 for clinicians to discuss a current consensus view on management of triple negative breast cancer however, until clinical trial data exists, healthcare professionals cannot exploit the benefits that emerging science could offer suffers of this particular tumour type.

Neptune Trail design
Tests the addition of Iniparib to chemotherapy against standard docetaxel

Additional research
Does iniparib work on its own in a maintenance role and upon which patients?
Iniparib with chemotherapy
Imaging sub studies – for future non-invasive monitoring

Summary

As a member of ICPV and as patient who has undergone treatment for Triple Negative Breast Cancer, the Neptune Trial is welcomed and urgently needed for this particular community of patients in order to improve outcomes in the longer term.

As one of the lesser understood tumour types in terms of clear treatment plans, the study group are clearly and, I believe, rightfully, aware that this may not be easy to recruit to. Despite this, I do believe that this is possible to address this significantly with some work. I am still of the belief that it remains important to further the evidence base for new and more effective treatment behind the emerging science.

Trial recruitment.

It may be challenging to communicate the necessity for this type of trial at diagnosis when many patients may not be fully aware of the more complex nature of their diagnosis.

Patient information and a clear understanding of the "different" characteristics of this type of tumour is more crucial for recruitment to trial as, without this, some patients may well be simply "put off" by the number of additional invasive interventions and additional visits. This could involve up 6 visits every 3 weeks for 14 weeks, some visits will be full days. This is a lot to ask of patients as are the additional biopsies required.

Timing is crucial to this trial and the speed at which patients will need to be recruited will necessitate excellent planning at trail design stage (is there any way that the number of visits could be reduced by revisiting the patient pathway?) The recruitment process will also need to be discussed in some detail as patients may need a two stage information process plus the opportunity to ask questions after reading/watching additional information. If this is not done effectively, there may be a risk that even if patients recruit, they may well drop out of the trail if they are not fully prepared.

What may assist in the effective communication and recruitment to trial?

Careful planning at trial design stage with discussion and input from patients alongside the study group.

Well informed, skilled staff with the time to explain carefully and sensitively, both the longer term implications of the diagnosis and also the details of the study. It may be helpful to consider supplementary communication support materials such as a DVD which patients can take home and watch privately. Both written information for patients and a DVD could be enhanced with direct input from patients to help communicate key messages.