

A randomised controlled phase III trial comparing hyperthermia plus mitomycin to a second course of bacillus Calmette-Guérin or standard therapy in patients with recurrence of non-muscle invasive bladder cancer following induction or maintenance bacillus Calmette-Guérin therapy

Issue 5

### Newsletter – May 2011



# Can't accommodate the Synergo device but still would like to take part in the trial? No Problem!

If your site is interested in joining the HYMN trial but you feel that you are not able to acquire or accommodate the Synergo device needed to give the experimental treatment you can still participate in the trial. For further details please refer to page 2 of this newsletter.

### **Current recruitment -Open sites**

our chi recruitment -open sites		
PI	Patients randomised	
Mr Ravi Kulkarni	0	
Mr Hugh Mostafid	6	
Mr Sanjeev Madaan	1	
Mr Leyshon Griffiths	2	
Mr Dominic Hodgson	2	
Mr John McGrath	0	
Mr Mike Bailey	5	
Miss Jo Cresswell	8	
Mr Mark Feneley	8	
Mr Vijay Sangar	3	
	Mr Ravi Kulkarni  Mr Hugh Mostafid  Mr Sanjeev Madaan  Mr Leyshon Griffiths  Mr Dominic Hodgson  Mr John McGrath  Mr Mike Bailey  Miss Jo Cresswell  Mr Mark Feneley	

### **Treatment Centres in set-up**

- Queen Elizabeth Hospital, Birmingham
- University Hospital of Wales, Cardiff
- St James's University Hospital, Leeds
- Pinderfields Hospital, Wakefield
- Charing Cross Hospital, London
- Churchill Hospital, Oxford
- Freeman Hospital, Newcastle

## Non-experimental Treatment centres in set-up

- Royal Berkshire Hospital, Reading
- Queen's Hospital, Burton
- Kettering General Hospital
- Derby City Hospital

### Current Essential Document versions

Protocol v2

PIS V2

PIS appendixes v1.1

**Consent form V2** 

New document versions QoL v1a (non-substantial amendment made this month)

#### **Patient Referral and Control Treatment Centres**

There are three main ways to get involved in the HYMN trial:

- 1 Become a full trial site "HYMN Treatment centre"
- 2 Become a control treatment only site "Non-experimental Treatment centre"
- 3 Refer patients to a consultant at a full HYMN site for trial consideration

If you are unable to accommodate the Synergo Hyperthermia device required for the trials experimental treatment (Hyperthermia plus Mitomycin) then you can still run the trial locally as a HYMN "non-experimental Treatment Centres". You will need to be located fairly near to a full HYMN treatment site but this way you will be able to identify, consent and randomised patients to the trial as well as still treating those patients that are randomised to the Control arm of the trial. Patients allocated to the Hyperthermia treatments will need to be referred to the nearby "HYMN treatment centres" and travel for their synergo treatments.

All sites operating this model of recruitment will share their recruitment accrual points. Centres will only be credited for the patients that they treat not randomised to ensure that both sites get some credit for the work that the put into the trial.

If your site is interested in joining the HYMN trial in this way please contact the trials office and we can put you in touch with a suitable treatment centre.

### The HYMN trials 1st Birthday!

This month see the HYMN trials 1<sup>st</sup> birthday with 1 year since we opened to recruitment.

The trial has been successful so far with lots of interested sites and 10 of our 20 required sites already open to recruitment. However the challenge now is to accelerate recruitment to a stable 8-9 patients randomised per month.

We are confident that as we continue to open new centres and our existing centres get to grips with the trial we will reach our target of 100 patients by the end of the year.



#### Recruitment clinic

In order to help identify any barriers to recruitment and to pass on good practice we have been be hosting regular recruitment clinics. These are short teleconferences when you can dial in to get advice on any trial problems.

The next clinic will be held on the 16th May, at 10.00am -10.30am.

All sites that are open, in set-up or that are considering joining the trial are welcome to join for advice or to ask questions to the other sites. If you wish to dial in please contact the HYMN trial office.











### **HYMN Website**

For trial updates, documents and information please visit the website. <u>www.HYMN.bham.ac.uk</u>

If you are a healthcare professional involved in the trial and you wish to access the documents contained within the investigator section please contact the HYMN trial office for the password.

Please help us reach our target of recruiting 242 patients over 3 years by circulating this newsletter to anybody that you think may be interested in the HYMN Trial

Any questions please contact the HYMN trial office, Tel: 0121 414 9524, E-mail: HYMN@trials.bham.ac.uk