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

Newsletter – August 2011

Issue 6

Extra! Extra! Read all about it!

It's been a busy time for the HYMN trial recently with articles in local newspapers, a master class session at a prestigious NHS meeting and even a double page feature in the NIHR Clinical Research Network newsletter! For more information, please see page 2 of this newsletter or the HYMN website.

Current recruitment –Open sites

Site	PI	Patients randomised
Ashford and St Peters Hospitals	Mr Ravi Kulkarni	0
Basingstoke and North Hampshire Hospital	Mr Hugh Mostafid	6
Charing Cross Hospital, London	Mr David Hrouda	0
Darent Valley Hospital, Dartford	Mr Sanjeev Madaan	1
Leicester Royal Infirmary	Mr Leyshon Griffiths	2
Queen Alexandra Hospital, Portsmouth	Mr Dominic Hodgson	2
Queen Elizabeth Hospital, Birmingham	Mr Rupesh Bhatt	0
Royal Devon and Exeter Hospital	Mr John McGrath	0
St Georges Hospital, London	Mr Mike Bailey	6
St Mary's Hospital, London	Mr David Hrouda	0
The James Cook University Hospital, Middlesbrough	Miss Jo Cresswell	8
University College London Hospital	Mr Mark Feneley	8
University Hospital of Wales, Cardiff	Mr Shibs Datta	0
Withington Hospital, Manchester	Mr Vijay Sangar	3

Centres in set-up

- Freeman Hospital, Newcastle; St James's University Hospital, Leeds and Churchill Hospital, Oxford

New Patient Sheet and Consent Form Approved

PIS V3
Consent Form V3

New documents approved in May 2011. These should now be in use at your centre. If you are still using version 2 please contact the HYMN office ASAP.

Cystoscopies

The Cystoscopy results are an important endpoint of trial so it's vital that they are on schedule.

This is a particular issue when a possible recurrence is seen by flexible cystoscopy and a rigid is then required. These are high priority cases and the rigid cystoscopy should be done within a month of the original!

If you are having difficulties in scheduling these, please let us and your PI know, as there may be a way to rectify this.

Consent process – Reduced Patient Visits

Concerns over the number of extra patient visits before treatment has led to some sites modifying their consent procedure. If you wish to reduce patient visits, please use the consent process suggested below.

For the standard consent procedure please see the protocol and trial guidelines.

1. **Initial Discussion and Information Sheet provision**
   Once the patient is aware of their recurrence, contact them by telephone and pos the PIS, or discuss during a standard hospital visit
2. **Thinking time and Follow-up call**
   Telephone call after 24h+ to ensure that they have received and understood the PIS + answer questions
3. **Written Consent (extra visit 1)**
   Patient attends hospital to sign Consent Form with the investigator or delegate, baseline bloods can also be taken here.

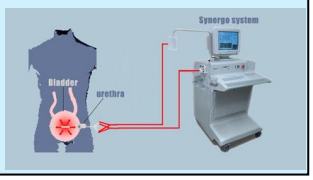
If your site is not using either of the recommended procedures, please contact the HYMN trials office ASAP so that we can check your process.

Extra Synergo Training Available

It is a trial requirement that all Synergo operating staff are trained directly by Medical Enterprises.

If some staff at your site have already received training, but additional staff are now required to use the Synergo system, please contact the trials office and we can arrange for an additional training course.

Please give us a minimum of 2 weeks notice if the training is required urgently.



Recruitment Tips

HYMN Poster: Put up in clinic areas to inform patients that your centre is participating in a trial.
Local network publicity: make sure all hospitals in your network have a copy of the eligibly criteria and know how to refer a patient to you.
MDT presentations: Give a presentation at your MDT so that the clinicians are aware of other, non-surgical options.

Recent Publicity

This year the HYMN trial has received positive publicity from a variety of sources. It started in February with a keen local PI writing a local press release to highlight the innovative work her team has been doing as part of the HYMN trial. This led to articles in several local and national newspapers, as well as the NIHR Clinical Research Network devoting a double page article to the trial in their June edition.

In the light of this publicity, the trial was also asked if they would like to present a Masterclass Session at the Innovation in Healthcare meeting in early May. Saying yes to the opportunity, we presented to a mixed audience of NHS managers, patient interest groups and clinicians. This meeting was a unique event supported by the Department of Health to showcase the best in healthcare innovation from the public, private, voluntary, academic and scientific communities.

Hopefully, this presentation together with the press and network interest has highlighted the importance of new innovations and clinical trials in bladder cancer management and especially the importance of the HYMN trial to patients where few treatment options remain.

Please see the HYMN website for copies of the press releases and articles.

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 Centre". 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 centre" and travel for their Synergo treatments.

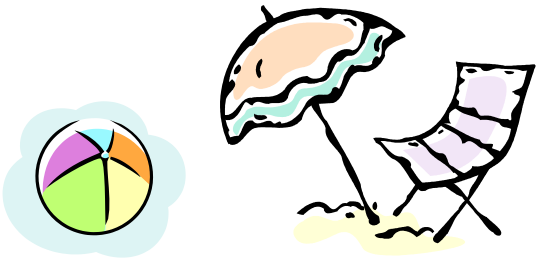
All sites operating this model of recruitment will share their recruitment accrual points. Centres will be credited only for the patients that they treat (not dependant on randomisations) to ensure that both sites get some credit for the work that the put into the trial.

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.

Data Returns

Data returns have been very poor of late. Please be reminded that On-study data such as Randomisation forms, Disease history forms, histology and On-study forms are required ASAP after the patient is randomised.

We are now sending monthly reminders of missing data by post but if you would prefer this by email, please let us know.



Screening and Patient history

Recently we have had some patients randomised using incorrect data, particularly in regards to previous BCG treatment. This is an important variable as it allows us to allocate the patients to the correct control treatment.

Please thoroughly check the patients' history prior to randomisation to ensure that you know the number of BCG treatments the patient has received and the most recent histology results.

We also recommend further screening procedures are carried out to ensure patients are eligible for trial treatment. For further guidance on this please see the *HYMN Screening Procedures* document (copy on the HYMN website).

Please also be reminded that it is important to record the patients' WHO status and the discussion regarding contraception in the patients' notes. If it is not relevant to discuss contraception with a particular patient, please write this in the notes too.

HYMN Website

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

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 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