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 – December 2011

Issue 7

The HYMN Trial has a new coordinator, Mrs Laurence Loubière.
She can be contacted on the usual trial telephone number, 0121 414 9524.

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	8
Darent Valley Hospital, Dartford	Mr Sanjeev Madaan	4
Freeman Hospital, Newcastle	Mr Toby Page	0
Imperial College Healthcare (Charing Cross & St. Mary's)	Mr David Hrouda	0
Leicester Royal Infirmary	Mr Leyshon Griffiths	3
Queen Alexandra Hospital, Portsmouth	Mr Dominic Hodgson	2
Queen Elizabeth Hospital, Birmingham	Mr Rupesh Bhatt	2
Queens Hospital, Burton	Miss Jyoti Shah	0
Royal Berkshire Hospital	Mr Peter Malone	0
Royal Devon and Exeter Hospital	Mr John McGrath	2
St Georges Hospital, London	Mr Mike Bailey	9
The James Cook University Hospital, Middlesbrough	Miss Jo Cresswell	10
University College London Hospital	Mr Mark Feneley	11
University Hospital of Wales, Cardiff	Mr Shibs Datta	1
Withington Hospital, Manchester	Mr Vijay Sangar	3

16 sites are now open to recruitment, 13 of which have the Synergo machine. This includes the one new site opened this month: **Freeman Hospital, Newcastle**

55 patients have now been randomised into the trial. Although recruitment since the last newsletter has been steady, we are hoping this will increase even more in the next few months.

Centres in set-up

Full HYMN Centres:
St James's University Hospital, Leeds
Churchill Hospital, Oxford
Non-experimental Centres:
Stepping Hill Hospital
Salford Royal Hospital
Whipps Cross University Hospital

HYMN-T Changes

Urine RNA and tissue slides will no longer be collected. The collection of HYMN-T samples will now be:

- **Urine DNA** (50mls, prior to cystoscopy) @ baseline, 3, 6, 9, 12 months and at recurrence
- **Whole blood** (baseline)
- **Paraffin block tissue** (any time after baseline)

Please contact Kathryn King if you have any questions about HYMN-T:

0207 679 6273
kathryn.king@ucl.ac.uk

HYMN Investigator's Meeting – St Georges Hospital, Friday 23 September 2011

Thank you to everyone who attended this useful meeting.
The main points arising from this meeting are:

1. **Changes to Institutional standard for patients who failed BCG maintenance** (> 6 instillations): Protocol amendments are in progress to allow the best standard therapy for BCG-failure to be chosen at the discretion of the treating clinician on a case by case basis.
2. **Patients on current and/or long-term corticosteroids** can be considered for HYMN. A protocol amendment is in progress but for the time being please contact the trial office before randomisation to confirm eligibility. The consultant who prescribed the corticosteroids will need to be notified of the HYMN treatment the patient will receive.
3. **A limited number of free HM treatments** (off trial) will be offered by Medical Enterprises for patients who fail treatment on the control arm. Please contact the trial office for further information if you have a patient who could benefit from this.

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 trial's experimental treatment (Hyperthermia plus Mitomycin) then you can still run the trial locally as a HYMN "non-experimental Treatment Centre" and refer patients allocated to the Hyperthermia treatment to a nearby full treatment site. This way you will be able to identify, consent and randomise patients to the trial as well as still treat those patients that are randomised to the Control arm.

Recruitment accrual points will be shared so that centres will be credited only for the patients that they treat (not dependant on randomisations) to ensure that both sites get credit for their work.

If interested, please contact the trials office and we can put you in touch with a suitable treatment centre.

Screening and Patient history

In the past some patients were 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.

Randomisation Procedures

There have been some changes to the information we require before a patient is randomised into HYMN.

The following documents must be sent to the trial office by fax before randomisation:

- **Eligibility Form**
- **Disease History Form**
- **Latest Pathology Report**
- **Latest CT Scan Report**
- **Randomisation Form**
- **On Study Form**

Please await confirmation of eligibility before randomising the patient using the usual randomisation numbers:

0800 7317625 / 0800 371969
(9:00 a.m. to 5:00 p.m)

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.

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.
(A Minimum of 2 weeks notice is required)

HYMN Website

For trial updates, documents and information:
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.

Recruitment Tips

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

Please don't hesitate to contact the HYMN trial office (either by phone or email) if you have any questions at all, particularly any concerns about eligibility.
Tel: 0121 414 9524, E-mail: HYMN@trials.bham.ac.uk

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.