



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 – January 2011



20 patients now randomised!

We also now have 8 HYMN trial sites open and with 10 Synergo systems placed in the UK we are on target to increase the number of active HYMN sites to 10 sites by the end of the month.

Sites open to recruitment

Site	PI	Patients randomised
Ashford and St Peters Hospitals	Mr Ravi Kulkarni	0
Basingstoke and North Hampshire Hospital	Mr Hugh Mostafid	2
Leicester Royal Infirmary	Mr Leyshon Griffiths	1
Queen Alexandra Hospital, Portsmouth	Mr Dominic Hodgson	1
St Georges Hospital, London	Mr Mike Bailey	4
The James Cook University Hospital, Middlesbrough	Miss Jo Cresswell	6
University College London Hospital	Mr Mark Feneley	5
Withington Hospital, Manchester	Mr Vijay Sangar	1

Treatment Centres in set-up

- Queen Elizabeth Hospital, Birmingham
- Darent Valley Hospital, Dartford
- University Hospital of Wales, Cardiff
- St James's University Hospital, Leeds
- Royal Devon and Exeter Hospital
- Pinderfields Hospital, Wakefield
- Charing Cross Hospital, London
- Churchill Hospital, Oxford

Protocol Amendment 1

As you may be aware in November the HYMN Protocol and Patient sheet amendment was released to sites following approval by the Ethics committee and the MHRA.

The new documents are:

Protocol Version 2

Patient Information Sheet V2

Consent form V2

Patient Card VI

This amendment has now also been approved by CSP and all global checks completed. If you have not already done so please contact your R&D department to gain the local approvals for these new versions.

Once local approval has been gained these new versions can be used.

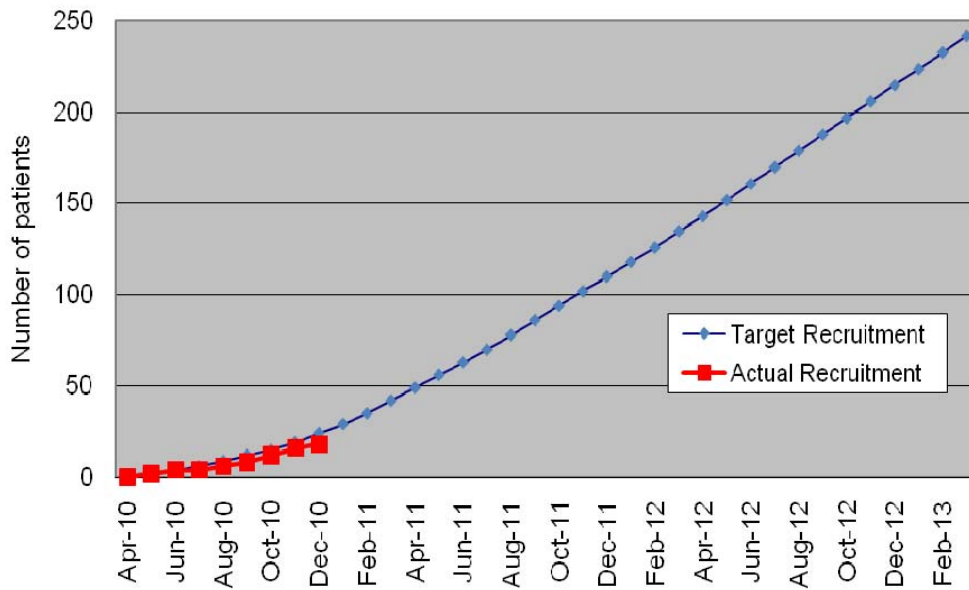
CRF's Version 2

Along with the new protocol and patient sheet versions we have also updated the CRFs. Please ensure that you are now working with the version 2 CRFs and Trial Guidance manual. If you require any copies of the new documents for your site file please contact the HYMN trial office.



Trial Recruitment

Graph of Actual Recruitment vs Target Recruitment for the HYMN Trial



20 patient randomised in 9 months

Recruitment is currently on track for this stage of the trial. However if we are to reach our total recruitment targets we need to increase recruitment over the next 6 months.

Recruitment clinic

In order to help identify and barriers to recruitment and to pass on good practice we will be arranging a recruitment clinic. This will be a short teleconference when you can dial in to get advice on any trial problems. The first clinic will be held in January, date and time to be confirmed.

Referral and Control Centres

We are also opening the following centres as HYMN "Control Treatment Centres". These centres will be able to filter patients to the larger "Experimental treatment centres" whilst still treating those patients that are randomised to the Control arm of the trial.

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

If your site is interested in joining the HYMN trial but you feel that you are not able to become an experimental treatment centre please contact the trials office.

Patients must be willing to travel!

Protocol Amendment 1 Essential document return

Please remember to return copies of the following documents to the trial office:

*Patient Information sheet and
Consent form V2 on local
headed paper.*

Protocol signature page V2

Pharmacy Version control V3

*R&D approval letter for the
amendment*



DMC

Last month the HYMN Data Monitoring Committee met for the first HYMN DMC meeting.

No safety issue have been identified but the trial will be reviewed again in 6 months to check that all is still running smoothly.

HYMN Website

www.HYMN.bham.ac.uk

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

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