



Current Recruitment – Open Sites

Site	PI	Patients Randomised
Experimental Centres		
Basingstoke and North Hampshire Hospital	Mr Hugh Mostafid	10
Darent Valley Hospital, Dartford	Mr Sanjeev Madaan	9
Freeman Hospital, Newcastle	Mr Toby Page	2
Leicester General Hospital	Mr Leyshon Griffiths	5
Queen Alexandra Hospital, Portsmouth	Mr Dominic Hodgson	3
Queen Elizabeth Hospital, Birmingham	Mr Rupesh Bhatt	8
Royal Devon and Exeter Hospital	Mr John McGrath	6
St Georges Hospital, London	Mr Rami Issa	11
The James Cook University Hospital, Middlesbrough	Miss Jo Cresswell	14
University College London Hospital	Mr Mark Feneley	17
University Hospital of Wales, Cardiff	Mr Shibs Datta	1
Withington Hospital, Manchester	Mr Vijay Sangar	6

Non-experimental Centres

Ashford and St Peters Hospitals	Mr Ravi Kulkarni
Imperial College Healthcare (Charing Cross & St. Mary's)	Mr David Hrouda
Stepping Hill Hospital, Stockport	Mr Richard Brough
Queens Hospital, Burton	Miss Jyoti Shah

Treatment Scheduling

Each patient's treatment should be completed within 24 months (20 instillations for HM, 21 for BCG).

If maintenance treatment is out of schedule, we ask that if possible the next treatment should be moved forward (i.e. usual duration between treatments reduced), keeping a minimum of 3 months between each maintenance cycle, in order to catch up and make sure that the correct number of instillations are received by the patient within the 24 months of treatment.



Cystoscopy Scheduling

It is important that the 3-month rigid cystoscopy is always performed after the induction treatment.

In addition, random four-quadrant biopsies must be taken for all patients that had CIS at baseline.

Subsequent cystoscopies should be arranged to fit the schedule as much as possible even if treatment is delayed from schedule.

Please note that for patients receiving, there must be a gap of at least two weeks between each cystoscopy and the next treatment.

92 patients have now been randomised into the trial.

Which site will be the one to recruit the

100th Patient?

16 sites are now open to recruitment, 12 of which have the Synergo machine.

Centres in set-up

Full HYMN Centres:

- Churchill Hospital, Oxford
- Homerton Hospital, London
- Cumberland Infirmary, North Cumbria University Hospital, Carlisle

Non-experimental Centres:

- Salford Royal Hospital
- Whipps Cross University Hospital, London

Recruitment has not been affected by the summer BCG crisis.

HYMN is on its way to being the largest study of patients with CIS in the UK

Please help us achieve our recruitment goal by continuing to enter any eligible patients into the trial

Patient Eligibility Criteria

Synergo catheters are bigger than usual catheters and have a solid piece in them so it is important to check when assessing eligibility that there is no issue such as urethral stricture or anything impeding the insertion of a 20F catheter.

Treatment and Cystoscopy delay

The delay is calculated from the date given in the patient schedule provided after randomisation.

The cystoscopy dates are calculated from the 1st trial treatment date. The protocol gives a +/- 14 days window from the scheduled date. If there is a delay, count the number of whole days from the beginning or the end of the window as appropriate.

For example if schedule date is 14-Nov-2012, a cystoscopy done between 31-Oct-2012 and 28-Nov-2012 is within the window and there will be no delay to be recorded. A cystoscopy done on 30-Nov-2012 will be 2 days out of schedule.

End of Treatment

Please complete an End of Treatment form when treatment is stopped. If the patient does not receive all of their scheduled treatment, this form should be completed in addition to a Withdrawal Form.

Quality of Life

It is important to ask each patient who has consented to the QoL sub-study to complete a questionnaire at each Surveillance visit and to then send these in to the trial office.

Current Trial Treatment box

'Current Trial Treatment' at the top of some of the CRFs refers to the treatment the patient was allocated at randomisation even if they have withdrawn from treatment.

The only exception is patients who are on exploratory treatment. This would then be the treatment they are currently receiving.

Feedback from investigator meeting

A HYMN Investigator Meeting was held on 24th September 2012. This was an opportunity for investigators and site staff to discuss recent developments and share their experiences of the trial.

The importance of local publicity was highlighted.

- Place **trial poster** in your clinic
- Mention the HYMN trial in the **hospital newsletter**
- Increase **patient referrals** by presenting the HYMN trial to local urologist meeting; make sure all hospitals in your network have a copy of the eligibility criteria and know how to refer a patient to you
- **MDT presentations**

Patients with recurrence or progression:

Please note that persistence of CIS at 3month in patient with CIS at baseline is not a recurrence.

If patients have a recurrence or a progression during their trial treatment, they go onto yearly follow-up: 3-monthly surveillance is still recommended, but a form only needs to be completed once a year to summarise these visits.

Exploratory Patients who have switched arms following a recurrence

For patients on exploratory treatment, treatment forms and surveillance forms should be completed for the new treatment received. Surveillance forms should be completed for any cystoscopies performed, beginning again at 3 months from the first exploratory treatment received. These visits will be at the clinician's discretion and will not necessarily follow the standard HYMN schedule, so please circle the Assessment Month closest to the time point from the first exploratory treatment received.

In addition, for those exploratory patients, the annual Follow-Up form should also be completed around the anniversary of the first trial treatment received.

Toxicity recording on Treatment forms

Please follow the following guidance when completing the

Toxicity assessment:

- if toxicity present but grade unknown:

0	1	2	3	4	NK
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
- if presence of toxicity unknown: cross through all grades and write NK:

0	1	2	3	4	NK
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

 NK

UK Representative for Synergo/Medical Enterprise Europe

The Synergo manufacturer, Medical Enterprises Europe, has appointed Speciality European Pharma (SEP) as their representatives in the UK and Germany.

SEP is a UK headquartered company focused on urology, with products in the therapeutic areas of bladder cancer, prostate cancer and overactive bladder.

Mr Rakesh Tailor is the General Manager of SEP in UK and will be your primary contact for any questions related to off-trial patients. He can also be contacted to help support your efforts with recruitment.

For all questions related to HYMN trial patients or technical aspects of the Synergo machine itself, please continue to contact Medical Enterprises Europe.

Rakesh Tailor, General Manager, UK & Ireland
Speciality European Pharma Ltd, 16 John Street, London. WC1N 2DL
Direct Tel: +44 (0)20 7421 7411
Main Fax: +44 (0)20 7421 7401
Mobile: +44 (0) 7850 368906
Email: rakesh.tailor@spepharma.com
www.specialityeuropeanpharma.com

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.

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 recruitment target of 242 patients by circulating this newsletter to anybody you think may be interested in the HYMN Trial.