

## NEWSLETTER

August 2008

**SHIELD: A phase II study of Hodgkin lymphoma in patients > 60 years.**  
[www.shieldstudy.co.uk](http://www.shieldstudy.co.uk)

**179 patients recruited**

**52 sites open to recruitment**

### Recruitment

Registration patients **101**  
VEPEMB study patients **78**

### Sites

Sites with full approval **52**  
Sites awaiting R&D approval **4**

### Europe

Cologne registered  
**57 patients**

Dear Investigator

We would like to take this opportunity to thank you for your support of the SHIELD Study and hope this will continue over the next year. SHIELD is now the largest Hodgkin's lymphoma study in the elderly. However, we need a real push to get over 100 VEPEMB study patients (in particular those with Stage 3 and 4) before the study closes in August 2009. We need this number to accurately assess remission rates and assess the full value of the VEPEMB schedule.

Some investigators are nervous of the use of bleomycin in the elderly population but the really good news on the toxicity front is that we have had no report of bleomycin pulmonary toxicity in VEPEMB treated patients. The study schedule delivers only half the amount delivered in ABVD, so this might be the reason.

We plan a number of laboratory investigations on original diagnostic pathology blocks and serum/plasma to assess potential factors in a new prognostic index for elderly Hodgkin lymphoma patients. Please ensure that representative blocks are sent to the Study Histopathologists when the request is received and ensure that blood samples are sent pre-treatment for VEPEMB patients.

Many thanks for your involvement and support.



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**Please remember:** Elderly Hodgkin's lymphoma patients who are too frail for the VEPEMB treatment, should be consented and registered on the database.

*Please remember to ask patients to complete: **QUALITY OF LIFE QUESTIONNAIRES**  
Before Treatment, at End of Treatment, at Year 2 and Year 5  
And send to Study Co-ordinator, Jennifer Wilkinson, at Newcastle Study Centre*

**NEW**

On-line database handbook (Version 6) for eCRF completion at:  
HomePage : [www.shieldstudy.co.uk](http://www.shieldstudy.co.uk)

A copy of the patient's HISTOLOGY REPORT will be requested by the Newcastle Study Centre to enable us to obtain histological material for central pathology review.

# UK RECRUITMENT

SHIELD STUDY RECRUITING CENTRES : JULY 2008

HOSPITAL	VEPEMB Patients	Reg. Patients	HOSPITAL	VEPEMB Patients	Reg. Patients
RVI, Newcastle	10	2	University College, London	0	1
Mid Stafford District Hospital	4	0	James Cook, Middlesbrough	2	2
Raigmore Hospital, Inverness	2	0	South Tyneside District General	2	0
Aberdeen Royal Infirmary	5	7	Trafford, (Manchester)	1	0
Sunderland City Hospitals	6	3	West Cumberland Hospital	5	1
Edinburgh Western General	0	5	Mount Vernon Hospital	2	4
Bradford Royal Infirmary	1	0	Western Infirmary, Glasgow	1	1
Harrogate District Hospital	1	0	Wishaw General Hospital	3	0
Northampton General Hospital	2	1	York Hospitals NHS Trust	0	1
Cumberland Royal Infirmary	1	0	Poole Hospital	1	0
North Tyneside General Hospital	1	0	Southampton Univ Hospital	4	0
East Kent Hospital	1	0	Ipswich Hospital NHS Trust	0	2
Kettering General Hospital	0	2	Royal Cornwall Hospitals	2	0
Blackpool, Fylde & Wyre Hospitals	3	0	Barnet General & Chase Farm	1	0
Medway, Kent	4	0	Christie Hospital, Manchester	0	4
Sheffield Royal Hallamshire	4	1	Gateshead Queen Elizabeth	1	0
Bournemouth Royal Hospital	0	1	Manchester Royal Infirmary	1	0
Royal Liverpool Hospital	1	0	Basingstoke & North Hampshire	1	0
University of Cologne	0	57	Pembury Hospital	0	1
			Monklands General Hospital	1	1

*Congratulations to Newcastle, Aberdeen and Sunderland – our top recruiters*

## DATA COLLECTION

*Would Principal Investigators and Trial Co-ordinators please ensure that the data for these patients is up-to-date on the electronic CRF. A preliminary analysis of the existing data will be prepared for the DMEC meeting in the Autumn.*

### Remember to record all ADVERSE EVENTS in the eCRF

#### ADVERSE EVENT

defined as:

"any undesirable sign, symptom, or medical condition occurring after starting study drug, whether considered study drug-related or not".

#### SERIOUS ADVERSE

EVENT defined as:

"(a) fatal or life threatening; (b) requires or prolongs hospitalisation; (c) significantly or permanently disabling; (d) a congenital anomaly; (e) any other significant medical event".

**Please notify us of any SAE within 24 hours by faxing SAE form (found at [www.shieldstudy.co.uk](http://www.shieldstudy.co.uk) HOMEPAGE) to SHIELD Study Centre at: 0191 222 5524.**

*Please remember to send before treatment begins:*

**5 ml of clotted blood (one red topped tube)  
5 ml of whole blood (EDTA tube)**

**Samples to be sent to:**

Dr T Mainou-Fowler, Academic Haematology,  
Newcastle University, Leech Building, Medical School,  
NEWCASTLE UPON TYNE, NE2 4HH.

**CONTACT:** [jennifer.wilkinson@ncl.ac.uk](mailto:jennifer.wilkinson@ncl.ac.uk) to obtain pre-paid sample boxes

