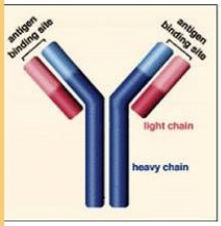
Number 1
December 2014

EudraCT No. 2012-003947-31
Ethics Ref: 13-NE-0361



OPTIMAL

Optimising Renal outcome **i**n **M**yeloma ren**al** failure

A study of Thalidomide, Bendamustine & Dexamethasone (BTD) Vs Bortezomib, Bendamustine & Dexamethasone (BBD) in patients with renal failure defined as GFR below 30 mls/min

Welcome to the OPTIMAL Trial first newsletter!

Thank you for all your expressions of interest in this trial– we are pleased to announce that we now have ethical and regulatory approval in place, Warwick CTU are ready to randomise our participants and we have begun recruitment into the trial at Oxford University Hospitals Trust!

XMAS OPENING HOURS

RANDOMISATION: Warwick Clinical Trials Unit will be closed between 24th Dec 2014 – 1st January 2015 inclusive. The randomisation line will re-open 2nd January 2015

To **randomise** a patient please call **Warwick Clinical Trials Unit** on: **02476 150 402**

DRUG ORDERS: The last drug orders before Christmas will be processed 19th December 2014. Any orders received after this date will not be processed until January 5th at the earliest. Please make sure you have sufficient drug supplies to last the festive period!

Please send completed **drug order forms** to: **optimal.trial@nhs.net**

OPTIMAL TRIAL OFFICE: the office will be closed Mon 22 Dec– Sun 4th Jan inclusive; for any urgent queries during this period please contact the Chief Investigator on **karthik.ramasamy@ouh.nhs.uk**

SAEs: Please continue to report all SAEs within 24 hours of awareness over the festive period using the **FAX NUMBER ONLY** as we will be unable to pick up email between Mon 22 Dec– Sun 4th Jan.

FAX SAEs to OPTIMAL Trial Office: **01865 572 035**

NEWSLETTER

Oxford University Hospitals NHS
NHS Trust

OPTIMAL

TRIAL UPDATE

The Churchill Hospital in Oxford opened to recruitment on 01 Dec 2014; we're keeping our fingers crossed they give us an early Christmas present of our first patient on trial!

We hope to open Royal Berkshire Hospital, Reading early in the New Year and then roll out opening in a first wave across the rest of the Thames Valley Sites (in no particular order):

- Buckinghamshire Healthcare NHS Foundation Trust
- Heatherwood and Wexham Park Hospitals NHS Foundation Trust
- Great Western Hospital, Swindon

This will be followed by a second wave taking in all our other sites nationwide!

NEW CRFs RELEASED! - please make sure you are using the updated versions. All updated CRFs are available from the optimal trial website: **http://nssg.oxford-haematology.org.uk/myeloma/optimal/optimal.html**

Thanks for your patience and all your expressions of interest….we are slowing rolling out recruitment to iron out any issues we have with data management and drug supply early to make it easier for you all later on. We really value your continued interest and support!

STUDY REFRESHER

Randomisation

Arm A [n = 60 patients]

Bortezomib, Bendamustine, Dexamethasone

Bortezomib Vs Thalidomide

Four 21 day cycles **OR** six 21 day cycles (if not for ASCT)

Arm B [n = 60 patients]

Thalidomide, Bendamustine, Dexamethasone

Follow-Up to End of Cycle 4 **OR** End of Cycle 6 (for those not for ASCT) +

Follow-Up at **one month** post final treatment +

Follow-Up at **12 months** post randomisation

PRIMARY ENDPOINT: Serum free light chain (sFLC) response to first 2 cycles of chemotherapy

CO-PRIMARY ENPOINT: Renal response at the end of 4 cycles of therapy

SECONDARY ENDPOINTS: at the end of 4 cycles of therapy (or significant toxicity)

- sFLC response and prediction based on 1st and 2nd cycle response
- Drug toxicity and overall survival

Dr Karthik Ramasamy;

Chief Investigator

Wishing you all a Merry Christmas– Looking forward to working with you on OPTIMAL Trial in 2015!

OPTIMAL

Merry Christmas from all the staff at OPTIMAL!!

MAIN INCLUSION CRITERIA

- Male or female, aged 18 years or above
- Patients with newly diagnosed symptomatic myeloma
- Glomerular Filtration Rate (GFR) <30 mls/min
- CKD stage 4 (15-29 ml/min) and CKD stage 5 (<15 ml/min)

  Where there is a pre-existing medical condition which may cause renal damage, there must have been a further decline (≥15 mls/min GFR) between previous steady state and the study screening
- Women of childbearing potential (WCBP) and male patients whose partner is a WCP must be prepared to use contraception and comply with the Thalidomide Celgene™ Pregnancy Prevention Programme
- Free of prior malignancies for ≥ 2 years *with exception of currently treated basal cell, squamous cell carcinoma of the skin, localised prostate cancer or carcinoma "in-situ" of the cervix or breast*

MAIN EXCLUSION CRITERIA

- Female participant who is pregnant, lactating or planning pregnancy during the course of the trial or the female partner of a male participant planning a pregnancy during the course of the trial
- Known allergy to investigational drugs
- Any of the following laboratory abnormalities: Absolute neutrophil count (ANC) < 1.0 x10^9/L; Platelet count <75 x 10^9/L; Serum SGOT/AST or SGPT/ALT >3 x upper limit of normal
- Use of any standard/experimental anti-myeloma drug therapy excluding dexamethasone 14 days prior to trial entry
- Intention to use a physical method of serum free light chain removal such as plasma exchange or high cut off dialysis
- Grade 2 neuropathy or more
- Participants who have participated in another research trial involving an IMP in the past 12 weeks
- Contraindicated to receive either one of the study drugs, thalidomide, bortezomib, bendamustine

STAFF AT OPTIMAL TRIAL OFFICE

Samuel Paul is your contact for data management; please contact him at **samuel.paul@ouh.nhs.uk**

For all other trial enquires please contact the Trial Coordinator on 01865 223 353 or **optimal.trial@nhs.net**

Chief Investigator: Dr Karthik Ramasamy **karthik.ramasamy@ouh.nhs.uk**

Sponsor: Oxford University Hospitals Trust

Funders: Janssen Cilag & NAPP Pharmaceuticals Ltd.

NEWSLETTER

Oxford University Hospitals NHS
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