COGNO
COOPERATIVE TRIALS GROUP FOR NEURO-ONCOLOGY

Member Newsletter

Issue 8 Winter/Spring 2010

Quick Update:

- Membership opened January 2008: currently 198 members
- CATNON: 1st COGNO patient registered!

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Message from our Chair

Welcome to the Spring edition of the COGNO newsletter. Your Executive have been busy with their fortnightly teleconferences ensuring that COGNO operations run like clockwork. We are only a few days away from our Third Annual Scientific Meeting and I am very excited by the quality of the invited speakers as well as being able to share the stage with the annual Neurosurgical Society of Australasia scientific meeting. Congratulations to Jenni Flynn, recipient of the COGNO travel grant to the ASM and thanks to Roche, MSD Oncology and Orphan Australia for their support of our ASM.

Our membership continues to increase and we are well aware that COGNO needs representation from all craft groups and consumers. Further, we are aiming to increase Regional and Rural membership.

I'm delighted to note that the EORTC "CATNON" study has finally come of age and the first Australian patients have been recruited. This has been an arduous and educative process for all concerned but it has demonstrated COGNO's ability to open a multi-national study and I am sure it has paved the way for subsequent studies. In addition, the local CABARET study is almost at the point of site submission. As you will read, the SEED study is also moving forward and will start to address the universal problem of steroid use in our patients.

I look forward to seeing many of you in Coolum.

STUDY & TRIAL UPDATES

SEED: *Self-reported evaluation of the adverse effects of Dexamethasone*

COGNO and the steroid working party have been very busy over the last few months in progressing the steroid concept into the pilot study SEED. The SEED study aims to assess the feasibility of patient reported outcomes in the evaluation of dexamethasone use in patients with brain tumours, brain metastases or advanced cancer. The study population of 100 will consist of 50 patients on ≥ 4mg/day of dexamethasone (and 50 associated caregivers). Of these 50 patients, 25 patients will have a primary brain tumour and the remaining 25 patients with brain metastases or advanced cancer, across up to 6 sites in NSW. The study chair is Dr Meera Agar.

The primary aim of the study is to assess feasibility and face validity revised version of the DSQ called the Dexamethasone Symptom Questionnaire Chronic (DSQ Chronic), both as a self report measure and as a caregiver proxy report, and to generate pilot data and information on the incidence and severity of symptoms and side effects that may be due to dexamethasone. The study will also assess the incidence of clinician rated side effects that may be attributable to dexamethasone. Other objectives will inform the feasibility of a phase II randomised placebo controlled study of a steroid sparing agent compared to dexamethasone alone in patients with primary brain tumour. The proposed steroid sparing agent for a future trial is acetazolamide (a diuretic) and this study will also measure baseline rates of symptoms which can be related to this drug to assist in determining the tolerability of adding acetazolamide therapy in this patient population.

Milestones include submission of a CINSW Research Innovation Grant completed in August and submission of the SEED project to the CINSW Clinical Research Ethics Committee for the September meeting.

We would like to take this opportunity to thank everyone involved for their hard work and efforts. For more information or queries please contact the team on seed@ctc.usyd.edu.au

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STUDY & TRIAL UPDATES cont.

CABARET Study: *A randomised phase II study of Carboplatin and Bevacizumab in Recurrent Glioblastoma Multiforme (GBM)*

The CABARET study is an investigator-initiated study coordinated by the NHMRC Clinical Trials Centre, University of Sydney under the auspices of COGNO. The study is supported by Roche. The primary aim of the CABARET study is to determine the effect of bevacizumab plus carboplatin versus bevacizumab alone on progression-free survival in patients with recurrent glioblastoma multiforme. The study will be conducted at up to 20 Australian sites, with a recruitment target of 120 patients over 2 years. Lead NSW ethics approval has been granted, sites selected and we are currently sending out ethics packs to sites. We are hoping to have the first patient recruited to the study by the end of 2010. Watch this space for further updates regarding this exciting new study!

CATNON (EORTC 26053-22054): *Phase III trial on concurrent and adjuvant Temozolomide chemotherapy in non-1p/19q deleted anaplastic glioma.*

The trial has reached another milestone since the last newsletter by registering the first COGNO patient. **Congratulations to Dr Helen Wheeler and A/Prof Michael Back, and their teams at the Royal North Shore Hospital (NSW) for recruiting the first patient!** Special mention to Dr Rosie Harrup and her trial team at Royal Hobart Hospital (TAS) who was recently activated and also registered their first patient. It was exciting to have finally randomised a patient and work through the processes to prepare these patients for trial entry.

We continue to work closely with other sites in Australia with their local ethics and research governance submissions, and other logistical requirements for activation. It is anticipated that Thank you to all the CATNON sites for their hard work and continued support. As always, the CATNON Coordinating Centre welcomes all queries and any assistance we can provide at catnon@ctc.usyd.edu.au

CATNON Sites Activated and Patients Registered (as of 15 September 2010)

Site Name	State	Principal Investigator	Date Activated	Number Registered	Number Randomised
Royal North Shore Hospital	NSW	Helen Wheeler	20-Aug-10	2	2
Royal Melbourne Hospital	VIC	Mark Rosenthal	3-Sept-10	0	0
Austin Health	VIC	Lawrence Cher	21-Jun-10	0	0
Royal Hobart Hospital	TAS	Rosie Harrup	8-Sep-10	1	0
Sir Charles Gairdner Hospital	WA	Anna Nowak	29-Sep-10	0	0
			Total	**3**	**2**

COGNO TEAM UPDATE

We take this opportunity to temporarily farewell Ann Livingstone (nee Ratcliffe) who will be on maternity leave for 12 months; and to welcome Trevor France, who joins the COGNO team to oversee the clinical trial project management during Ann's leave. Trevor comes to the group with 15 years experience in drug development and life cycle management. The past 7 years Trevor has worked for Schering-Plough in clinical trial management.

Trevor France Ann Livingstone

MEMBERSHIP UPDATE

We are pleased to announce that we now have 198 members!

Help us expand our Group's expertise and networking capacity. If you know someone who would like to join, you can now refer prospective members to our online membership application on our website (www.cogno.org.au) or to the COGNO Coordinating Centre on cogno@ctc.usyd.edu.au