
NEXT OPEN FORUM: ADELAIDE, OCTOBER 2008

The next ASTN Open Forum will be held on 1 October 2008 alongside the ASA Annual Scientific Meeting in Adelaide. There will be a varied program which will appeal to clinical trials researchers from all areas of sleep research, with trials in somnambulism and non-CPAP therapies for OSA already on the agenda. If you have an interest in clinical trials, register for this meeting at no cost by selecting the ASTN Open Forum as a 'conference add-on' in your ASA conference registration form at <http://www.sleepaus.on.net/meetings.html>, or by sending an email to Melanie Harris, ASTN National Research Manager (melanie.harris@rgh.sa.gov.au).

ADELAIDE SEMINAR ON CAREER DEVELOPMENT

As well as holding the Adelaide Open Forum at the 2008 ASA Annual Scientific Meeting, the ASTN will co-host a symposium with the ASA Research Committee. The symposium, *Opportunities and Challenges in Building a Research Career in Sleep and Chronobiology Research*, will give researchers at any stage of their career insights into obtaining grant funding, fellowships, doctoral and post-doctoral positions, and on publishing, presenting and building up a CV. Details will soon be appearing on <http://www.sleepaus.on.net/meetings.html>, or contact ASTN Chief Investigator Naomi Rogers (nrogers@med.usyd.edu.au).

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ASTN SEEKS STAKEHOLDER FEEDBACK

It is now about two years since the ASTN began work to facilitate investigator-driven multi-site clinical trials in sleep health. Over this time the ASTN has put in place biostatistics and health economics expertise and a committee to evaluate and assist with research proposals, produced a website, newsletters and email information notices, and held Open Forum meetings and trial-development activities.

The ASTN Executive Committee would now like people interested in sleep health clinical trials to provide feedback on work to date to help with planning of future activities. If you have an interest in investigator-led clinical trials in sleep health and haven't yet completed an ASTN survey, please use the following link to fill out a brief anonymous questionnaire:

http://www.surveymonkey.com/s.aspx?sm=0NndLAmidjTCFCO_2bHDiWEA_3d_3d

ASTN Executive Committee members, Ron Grunstein, Doug McEvoy, Rob Pierce, Naomi Rogers, Lyle Palmer, Guy Marks, James Douglas and Shantha Rajaratnam wish to thank researchers who provide feedback.

STUDY DEVELOPMENT GROUPS IN 2008

All four ASTN steering groups set up in 2007, in the fields of insomnia, shift work, non-invasive ventilation and paediatric sleep health, initiated multicentre clinical trials protocols which were submitted early this year for NHMRC grant funding. Facilitation and specialist expertise was provided by the ASTN but credit for the development of these studies goes largely to the skills, hard work and collegiality of the steering and investigator groups themselves. Read more about the studies in the report on the Melbourne Open Forum (page 3).

The groups will continue during 2008, to further develop the first round of studies but also to explore further study ideas. Steering group leaders are keen to hear from people who would like to contribute to the development of new studies in 2008.

Contact details are:

Insomnia group: Simon Smith (simon.smith@qut.edu.au)

Shift work group: Shantha Rajaratnam (Shantha.Rajaratnam@med.monash.edu.au)

Non-invasive ventilation group: Amanda Piper (ajp@mail.med.usyd.edu.au)

Paediatrics group: Gill Nixon (gillian.nixon@southernhealth.org.au)

ASTN ENDORSEMENT FOR FUNDED TRIALS

Many groups are now accessing ASTN resources to develop clinical trials and to gain endorsement before applying for funding, but it is also possible to gain ASTN endorsement after receiving funding. If you have secured funding for a multi-site clinical trial and would like to have ASTN endorsement and access to specialist expertise for the conduct of your study, contact the ASTN by emailing Melanie Harris, ASTN National Research Manager (melanie.harris@rgh.sa.gov.au) or phoning (08) 8275 1952.

POSSIBLE TRIALS IN SURGICAL MANAGEMENT OF SLEEP DISORDERED BREATHING

A preliminary workshop of sleep physicians and otolaryngology, head and neck surgeons was held in Sydney in March to look at possible trials evaluating surgical treatments for sleep disordered breathing. Professor B Tucker Woodson of the Medical College of Wisconsin, an internationally known expert in surgical management of sleep disordered breathing, was a valuable contributor at the workshop. Workshop participants also gained new insights from the surgical clinical trials expertise of Professor Michael Solomon and Dr Jane Young of the Surgical Outcomes Research Centre (SOURCE) in Sydney. Several study ideas were generated and these will be further evaluated using SOURCE methodology before detailed development. The group supported further work on multicentre surgical trials with the establishment of small multidisciplinary groups to coordinate particular studies. To find out more, contact Keith Wong of the Woolcock Institute (keithkhw@gmail.com) or Melanie Harris, ASTN National Research Manager (melanie.harris@rgh.sa.gov.au).

REPORT ON MELBOURNE OPEN FORUM

Talks given by Lyle Palmer, Duncan Mortimer and study investigators were highlights of the 30 March ASTN Open Forum at the 2008 TSANZ scientific meeting in Melbourne.

Lyle Palmer's wide-ranging update on advances in genomics and pharmacogenomics included an explanation of genome-wide association (GWA) studies. This new type of study enables researchers to explore the genomes of large numbers of cases and controls for associations between single nucleotide polymorphisms and the disease of interest. GWA studies have already revealed single nucleotide polymorphisms associated with important diseases such as diabetes, heart disease, Crohn's disease, and some cancers. Delegates heard how these advances in genomics offer promise, for example, in reducing resource wastage by targeting therapies to patients with the appropriate genetic profile. National and international consortia are now needed to bring together the large sample sizes required for GWA studies on other diseases.

Duncan Mortimer, ASTN health economics consultant, outlined the three main types of economic evaluation that can be carried out in association with a clinical trial: within-trial and modelled economic evaluations and budget impact analyses. Each type has different purposes, methods, and advantages and disadvantages. For example, within-trial analyses are based on high-level evidence but often miss some important costs and effects while modelled analyses can be more complete but rely on lower-level evidence. Budget impact analyses identify the additional funding burden (or savings) that will be borne by a funding agency in the event that the evaluated intervention is implemented. As each type of analysis provides different information and has different limitations, ideally, health decision-makers should have access to all three kinds.

Four investigator presentations featured proposed trials in different fields of sleep health. James Douglas outlined the protocol and discussed methodological issues for the COMISA trial, which aims to test the benefit of treating both insomnia and OSA in patients with co-morbid insomnia and OSA. Physicians and psychologists at five sites across Australia worked together to design this pragmatic randomised controlled trial. Mark Howard spoke about NOVO, a multicentre trial to evaluate three types of positive airway pressure ventilation for people with obesity hypoventilation syndrome. Mark discussed decisions which were made during trial development on issues such as inclusion/exclusion criteria, selection of outcome measures and genetic predictors of ventilatory failure. Gill Nixon presented on the POSTA-Child study, which would be the first randomised controlled trial of adenotonsillectomy in paediatric OSA. Paediatricians, surgeons and psychologists from Queensland, New South Wales, Victoria, South Australia and Western Australia joined with trial design and health economics experts from the ASTN to develop this trial of adenotonsillectomy for neurocognitive outcomes in pre-school children who have mild to moderate OSA. Gill gave an interesting summary of the strengths of such a study and the challenges of putting together such an ambitious protocol. Shantha Rajaratnam spoke on behalf of LAPS investigators who have designed a three-site trial of a light-based intervention for alertness in shift workers. Randomised trials are uncommon in chronobiology research and this trial is designed to rigorously test a practical intervention in a work-like setting and in shift worker subjects. The protocol includes a search for genetic differences associated with individual differences in responsiveness to light.

The final investigator presentation was an update from SAVE Principal Investigator Doug McEvoy. Doug briefly summarised the methods for this international trial which aims to provide definitive evidence of the effect of CPAP therapy on cardiovascular events in people with OSA. Sites have been established in various centres in China and planning is now going ahead in other countries including New Zealand and Australia. Doug outlined the organisational structure required for the administration of such a large-scale trial.

The meeting closed with the ASTN Executive encouraging researchers to continue to make use of this NHMRC-funded facility for multicentre clinical trials in sleep health. If you are interested in joining or initiating multicentre trials, or would like further information on the presentations from the Open Forum, contact Melanie Harris, ASTN National Research Manager (melanie.harris@rgh.sa.gov.au).