

AHCC Trials Group

Newsletter Oct 2013

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AHCC Trials Group

Group Chair:

Prof Soo Khee Chee

Protocol Chair, AHCC06:

Prof Pierce Chow

Trials Group Website:

<http://www.scri.edu.sg/index.php/ahcc-trials-group>

Trial Coordinating Centre:

The Buzz

AHCC06 First Interim Analysis

Greetings to all members of the AHCC Trials Group!

This issue of our Newsletter highlights the 1st interim analysis of the AHCC06 trial which was conducted by the independent Data Monitoring Committee (DMC) on the 22nd May 2013. The committee comprised of Dr Thomas Leung (Chairman), Prof David Machin and Prof Bruno Sangro. The DMC met at the SCRI in Singapore, with Prof Bruno participating via videoconferencing. The committee found the overall conduct of the trial to be good and recommended that the trial to continue in its present form. This is an important affirmation of the trial and a major milestone.

We would like to thank the DMC Committee for their time and contribution in the Interim Analysis. We would also like to thank the sites and the SCRI team for their continued commitments and ensuring the Interim Analysis ran smoothly. It is an important milestone for the trial and the positive Interim Analysis is a validation of the capability of the team.



Ms Sandra Hsing (CRA), Ms Janice Ng (CRA), Dr Mihir Gandhi (Trial Statistician), Prof Pierce Chow (Protocol Chair), Prof Machin (DMC Member), Prof Sangro (DMC Member), Dr Leung (DMC Chair), Ms Sophie Moss (Project Manager and Mr Xia Yu (CRA) at the meeting.

AHCC06 Ancillary Study:

Prospective study on the utility of

¹⁸F-Fluorocholine in documenting metabolic response to y90 and Sorafenib therapy in locally advanced HCC

Principle Investigator:

Dr Wong Jen San,

Singapore General Hospital

This proposal was presented during the AHCC06 Investigators' Meeting last November. We are thrilled to share that the study has been approved for funding by the National Medical Research Council (NMRC) Singapore.

The study will leverage on the logistics of AHCC06. The aims of this study are

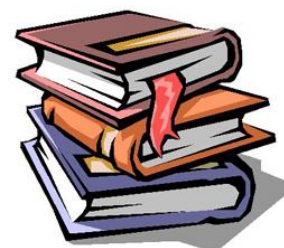
- To evaluate if there is correlation between changes in tumoural size (RECIST) and enhancement (mRECIST) and metabolic activity of HCCs (¹⁸F-Fluorocholine PET/CT).
- To evaluate if change in metabolic activity is a better assessment of response to treatment.

Dr Wong Jen San is currently planning the initial steps of implementation.

Published

"Conducting randomised controlled trials across countries with disparate levels of socio-economic development: The experience of the Asia-Pacific Hepatocellular Carcinoma Trials Group." was published in Contemporary Clinical Trials in May 2013.

Kong, N. H. Y. and P. K. H. Chow (2013). "Conducting randomised controlled trials across countries with disparate levels of socio-economic development: The experience of the Asia-Pacific Hepatocellular Carcinoma Trials Group." Contemporary Clinical Trials.



Investigators in Town

Prof Khin Maung Win (AHCC06 Site PI of Yangon GI & Liver Centre, Myanmar) was in Singapore for the 23rd Conference of the Asian Pacific Association for the Study of the Liver (APASL 2013) on 6 – 10 June 2013. The AHCC and SCRI study team hosted Prof Khin and his team for a dinner during the conference.



Prof Khin and his team in Singapore for the 23rd Conference of the Asian Pacific Association for the Study of the Liver.

AHCC06 (SIRveNIB)

Phase III Multi-Centre Open-Label

Randomized Control Trial of Selective Internal Radiation Therapy (SIRT) Versus Sorafenib in Locally Advanced Hepatocellular Carcinoma

Protocol Chair:

Prof Pierce Chow, NCCS, SGH and Duke-NUS

Study Status:

As of the 15th September 2013, there are 27 actively recruiting trial sites. The latest site to join the trial is The Brunei Cancer Centre (TBCC) in Bandar Seri Begawan, Brunei, initiated on the 3rd September 2013. Currently, 208 patients have been enrolled with the total sample size of the trial being 360 patients.

The trial had its scheduled first Interim Analysis on the 22nd May 2013 and we are pleased to share that the independent Data Monitoring Committee (DMC) found the trial to be on track with no safety issues. The positive DMC report is an affirmation of the study team's management of multi-centre trials. Click [here](#) to see the media release on the SGH website (www.sgh.com.sg).

Moving forward, the study team is anticipating the successful activation of 2 new Taiwanese sites, China Medical University Hospital and Kaohsiung Chang Gung Memorial Hospital. The study team will be conducting a Site Qualification Visit at a prospective site, Sarawak General Hospital in October 2013.

We look forward to having all of our sites participating and seeing patient enrolment continues to rise.



Media Release, July 2, 2013

Interim analysis found SGH-led SIRveNIB regional phase III clinical trial to treat patients with locally advanced liver cancer right on track

Singapore General Hospital, Newsroom

For more details on the AHCC06 trials, please visit <http://www.scri.edu.sg/index.php/clinical-trials>

Participating Centres:

Brunei:

- The Brunei Cancer Centre

Hong Kong:

- Queen Mary Hospital

Indonesia:

- University of Indonesia
- Sanglah General Hospital

Korea:

- Asan Medical Center
- Korea Anam University Hospital
- Seoul National University Bundang Hospital
- Seoul St. Mary's Hospital
- Severance Hospital
- St. Vincent's Hospital

Malaysia:

- Penang Adventist Hospital

Mongolia:

- National Cancer Center

Myanmar:

- Yangon GI & Liver Centre

New Zealand:

- Auckland City Hospital

Philippines:

- Makati Medical Center
- St. Luke's Medical Center
- The Medical City
- Davao Doctors Hospital

Singapore:

- Changi General Hospital
- Khoo Teck Puat Hospital
- National Cancer Centre
- National University Hospital
- Singapore General Hospital

Taiwan:

- National Taiwan University Hospital
- Chang Gung Memorial Hospital, LK
- Taipei Veterans General Hospital
- China Medical University Hospital
- Kaohsiung Chang Gung Memorial Hospital

Thailand:

- Chulabhorn Hospital

Site Initiation Visits

The Brunei Cancer Centre, Bandar Seri Begawan, Brunei

The Brunei Cancer Centre (TBCC) is a newly established cancer centre; it was previously part of the Raja Isteri Pengiran Anak Saleha (RIPAS) Hospital. TBCC is located at the Jerudong Park Medical Centre (JPMC). JPMC is situated within the famous Jerudong Park area, and is located on the shores of the South China Sea with patient rooms facing an expanse of beautiful, private beaches.

Dr Kenneth Kok is Site PI and also the Medical Director of TBCC. He leads a multi-disciplinary team that provides comprehensive care for cancer patients.

The study team from SGH and SCRI visited the facilities at TBCC on the 2nd September 2013, followed by the Site Initiation Visit on the next day. Prof Chow also took the opportunity to conduct a CME (Continuing Medical Education) session at TBCC. The topic “The Multidisciplinary Management of Hepatocellular Carcinoma” was well-received.

The study team is positive on this collaboration.

Site PI: Dr Kenneth Kok



From left, Mr Kenneth Kok (Site PI) and Prof Pierce Chow (Protocol Chair) during the SIV at TBCC.



SIV at TBCC



The study team from Singapore and Brunei posing in front of the future TBCC site.



*Dr Teoh Yee Leong,
CEO of SCRI*

SCRI – who's who

We warmly welcome Dr Teoh Yee Leong to the AHCC06 study team!

Dr Teoh is a Public Health Physician with extensive expertise in the area of clinical research and public health. Prior to his appointment as CEO of SCRI in May 2013, he was Vice-President and General Manager for Emergent Biosolutions Asia Pacific. In that role, he was involved in the development of various vaccines and immunotherapeutic for this Biotech organization. He was also Director, Clinical Research and Medical Affairs for GlaxoSmithKline Singapore, Malaysia and Brunei from 2000 to 2005 where he conducted one of the largest Phase 3 clinical trials in Singapore involving more than 6,000 subjects for a Rotavirus vaccine.

Dr Teoh's other previous senior appointments in the public sector included being Assistant Commissioner of Public Health (Ministry of the Environment), Head, Jurong Polyclinic (National Healthcare Group Polyclinics) and Infectious Disease Epidemiologist (Communicable Disease Centre, Singapore). He has also been involved in several epidemiological studies and clinical trials in Singapore prior to joining the pharmaceutical sector in 2005.

Read more about all trials under AHCC at <http://www.scri.edu.sg>.

Contact Details

Network Secretariat:

- **Ms Lynette Lai** lynette.lai.s.h@sqh.com.sg
DID: (65) 6576 2151
Fax: (65) 6220 9323
- **Ms Nicole Kong** nicole.kong.h.y@sqh.com.sg
DID: (65) 6326 6450
Fax: (65) 6220 9323

Mailing Address: 31 Biopolis Way Nanos #02-01 Singapore 138669

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Thank you all for your continued support of the AHCC Trials Group, please continue to let the Network Secretariat know of the ways that we can do even more together.