

AHCC Trials Group

Newsletter Jan 2013

The Buzz

AHCC06 (SIRveNIB) Investigator's Meeting 16 Nov 2012, Singapore



Pictures and names of participants can be found on the AHCC Trials Group website,
<http://www.scri.edu.sg/index.php/latest-events-updates/329-ahcc06-investigator-meeting>

The AHCC06 trial held its second Investigator's Meeting in Singapore at the Grand Copthorne Waterfront Hotel on 16 November 2012, a day before the 1st Asia Pacific Symposium on Liver Directed Y-90 Microspheres Therapy. This highly anticipated meeting saw the participation of more than 50 study investigators and coordinators from across Asia. The meeting provided an important opportunity to highlight recent changes to the protocol, review overall study progress, and share site specific issues, challenges and best practices.

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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:

AHCC06 (SIRveNIB) Investigator's Meeting, 16 Nov 2012



Dr Janus Ong gave an interesting presentation on his experience in the trial.



Prof Khin Maung Win shared his experiences in the trial. Myanmar has the highest number in recruitment.



Dr David Ng presented the workflow for SIRT at SGH.

Dr Ariunaa, Dr Brian Goh, Dr Hwang Dae Wook, Prof Pierce Chow, Dr Ian Cua and Dr Janus Ong at the Investigator's Meeting.

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The meeting kicked off with a welcome address by Protocol Chair, Prof Pierce Chow. Project Manager, Ms Sophie Moss, gave an overall update on the progress of the AHCC06 / SIRveNIB trial since the last Investigator's Meeting in 2011 including welcoming three new sites in Thailand and Taiwan. Two center PIs, namely Dr Janus Ong and Prof Khin Maung Win shared their experiences and best practices. Last but not least, 3 ancillary studies were presented and approved by the group.

Dr Janus Ong from The Medical City, Philippines focused on "How to achieve consistent patient recruitment". Dr Ong presented his experiences in the trial, sharing insights and advice with the group.

Prof Khin Maung Win from Yangon GI & Liver Centre, Myanmar shared on "Patient Recruitment, Retention and Follow-Up". He shared successful strategies used to increase subject recruitment and to retain patients. These strategies include use of media to create awareness and developing good personal rapport between patients and study staff.

Further best practices were shared by Dr David Ng, who covered Singapore General Hospital SIRT Workflow Processes for overseas patients and some of the common difficulties encountered.

In addition, proposals for 3 ancillary studies to AHCC06 trial were presented to the group by Dr Brian Goh and Dr Teo Jin Yao. This stimulated much scientific debate and constructive feedback, with all 3 proposals being approved to move forward to the next stage of protocol development and funding application.

Overall, it was a stimulating and rewarding agenda, with the meeting itself enabling professional networking within the trials group. The study team would like to extend their thanks to the investigators and guest speakers for making this event a success.



Highlights

AHCC06 (SIRveNIB)

Phase III Multi-Centre Open-Label Randomized Control Trial of Selective Internal Radiation Therapy (SIRT) Versus Sorafenib in Locally Advanced Hepatocellular Carcinoma

Study Status:

As of November 2012, 24 sites (5 in Singapore, 19 overseas) have been initiated, 5 centres joined in 2012 and 5 more centres are in the process of IRB approval and SIV. 151 subjects have been recruited. All centres submitted new annual recruitment figures and are committed to achieving their target recruitment numbers by the end of 2013! Our thanks go to every site for their commitment to the trial.

As the trial is ramping up and a further 209 subjects await recruitment, 3 ancillary studies to the main trial have been put up to capitalise on the logistics already established. The ancillary studies were presented during the Investigator's Meeting and were approved by the group. The 3 ancillary projects are in the process of grant applications.

The latest AHCC06 trial protocol, version 5.0, was updated on 9 July 2012 and has been circulated to the sites for IRB/RA approval as necessary.



Pre-IM Dinner at Grand Copthorne Waterfront Hotel

Visit the AHCC06 Website at:
<http://www.sirvenib.com/>

Participating Centres:

Brunei:

- RIPAS Hospital

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

New Sites Soon to be Initiated!

We are pleased to welcome three new sites to the AHCC06 trial! IRB/EC submission is currently in progress at all three sites and site initiation visits are scheduled to take place in 2013 once IRB/EC approval is granted at each site. Once completed, there will be a total of 29 participating sites across 12 countries in Asia-Pacific!

Chulabhorn Hospital, Bangkok

The site qualification visit for Chulabhorn Hospital (CH), the latest center in the AHCC06 trial was conducted on 13 September 2012.

Chulabhorn Hospital is the first comprehensive cancer centre in Thailand initiated by Princess Chulabhorn. Site PI, A/Prof Chanisa, and her team gave us a very warm welcome to the hospital. We inspected site facilities and departments including – PET /Nuclear Medicine, Radiology and Pharmacy. The facilities are of a high standard and met all trial requirements. Protocol Chair, Prof Chow presented the AHCC06 trial study overview to A/Prof Chanisa and her team. We look forward to the Site Initiation Visit!

Site PI: A/Prof Chanisa Chotipanich
Current Status: IRB approved
Estimated SIV Date: Jan 2013



China Medical University Hospital, Taiwan

Site PI: Dr Peng Cheng Yuan
Current Status: IRB submission in progress
Estimated SIV Date: Feb 2013



Kaohsiung Chang Gung Memorial Hospital, Taiwan

Site PI: Prof Chen Chao Long
Current Status: IRB Submission in progress
Estimated SIV Date: Feb 2013



高雄長庚紀念醫院
 Kaohsiung Chang Gung Memorial Hospital

Ancillary Studies:

During the AHCC06 Investigator's Meeting, Dr Brian Goh and Dr Teo Jin Yao presented 3 ancillary studies of AHCC06 trial to the group.

The 3 studies are:

1. Prospective study on the utility of 18F-Fluorocholine in documenting metabolic response to y90 and Sorafenib therapy in locally advanced HCC – spearheaded by Dr Wong Jen San
2. Prospective study of the recovery of liver functional reserve after Y90 Therapy in locally advanced HCC as measured by the indocyanine-green retention test – spearheaded by Dr Teo Jin Yao
3. Prospective study of the correlation of serum biomarkers with response to Y90 and Sorafenib Therapy in locally advanced HCC – spearheaded by Dr Brian Goh

The presentation stimulated an intensive discussion and drew valuable feedback from the floor. All three proposals were well received by the group and would progress to the next stage of protocol development and funding application.

To date, the AHCC Trials Group has launched 6 multi-center AHCC clinical trials (5 Investigator-initiated) and has grown to include over 30 centers in the Asia Pacific. The multi-center AHCC06 trial is the largest trial to date of the AHCC Trials Group.



Dr Teo Jin Yao presenting the prospective study of the recovery of liver functional reserve after Y90 Therapy in locally advanced HCC as measured by the indocyanine-green retention test.



Prof Khin from Myanmar shared his valuable feedback on the studies.



The 3 ancillary studies created much interest and debate from the group.





SCRI Clinical Research Associates – who’s who?



From front left, clockwise: Ms Rebecca Loh, Ms Sandra Hsing, Ms Janice Ng, Ms Sophie Moss, Ms Isabelle Lee, Mr Xia Yu and Mr Liew Wei Ming

Since the last newsletter, there has been a change of personnel at the Singapore Clinical Research Institute, and five new Clinical Research Associates have been tasked with monitoring the AHCC06 trial. They are led by Project Manager, Ms Sophie Moss and Head of Department, Ms Isabelle Lee.

Sophie has a Master’s Degree in Biochemistry from the University of Oxford and has 5 years of experience in the Pharmaceutical Industry. She worked as a Brand Manager with GlaxoSmithKline UK previously. Sophie recently moved to Singapore and we wish her all the best settling into her new life and job here in the little red dot.

We would like to take this opportunity to give them a warm welcome to the AHCC Trials Group family!

Contact Details

Network Secretariat:

- Ms Poh Sze Phing szephing.poh@scri.edu.sg
DID: (65) 6508 8356
Fax: (65) 6508 8317
- Ms Lynette Lai lynette.lai.s.h@sgl.com.sg
DID: (65) 6576 2151
Fax: (65)6220 9323
- Ms Nicole Kong nicole.kong.h.y@sgl.com.sg
DID: (65) 6326 6450
Fax: (65) 6220 9323



From left, Lynette, Sze Phing and Nicole

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

Acknowledgements:

National Medical Research Council Singapore, SingHealth Foundation, PsiOncology, Sirtex Medical and Bayer Pharmaceutical for support of our clinical trials, past and present

