

AHCC Trials Group

Newsletter January 2017

The Buzz

AHCC07 and AHCC08 launched!

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AHCC Trials Group Secretariat

AHCC Trials Group

Group Chair:

Prof Soo Khee Chee

Protocol Chair, AHCC06:

Prof Pierce Chow

Trial Coordinating Centre:



Dear AHCC Trials Group members,

Warm greetings for the festive season.

As 2016 has drawn to a close, the AHCC Trials Group would like to give an overview of the significant events that have taken place in 2016. Our AHCC06 SIRveNIB clinical trial has reached its endpoint and is now in the closeout phase. The AHCC06 study team will be working with the study team of our sister trial, SARAH to conduct a prospective meta-analysis on the combined databases with an effective sample size of 760 patients.

In addition, we have launched 2 large prospective studies, AHCC07 and AHCC08 that would place the AHCC Trials Group in the forefront of liver cancer research. With these 2 new studies, the AHCC Trials Group has grown to more than 50 members. We welcome our new members from China, Korea, Japan and Thailand.

We look forward to the release of the AHCC06 results and more exciting collaborations, possibilities and opportunities in 2017.

Thank you for your support for the AHCC Trials Group. We wish everyone joy and peace throughout the new year.

AHCC06 (SIRveNIB)

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

Recruitment reached and Final Analysis triggered

The AHCC06 trial has reached a huge milestone in completing the recruitment of 360 patients on 22 May 2016.

The centres with the highest recruitment numbers are Yangon GI & Liver Centre, Mongolia National Cancer Centre and The Medical City, Chulabhorn Hospital and National Cancer Centre Singapore.

The final analysis was triggered and the data was locked on 13 September 2016 and the study is currently in the close-out phase. The study team is currently cleaning up the data for analysis and the result will be out first half of 2017.

Manuscripts for publication would be submitted in the first half of next year and the in-print publications will follow closely after.

A meta-analysis (VESPRO) to compare the SARA trial with the SIRveNIB trial will also be conducted. Using the combined datasets, VESPRO will compare the overall survival of Y90 versus sorafenib.

News on completion of AHCC06 – SIRveNIB subject enrolment was released at PRNewswire on 06 June 2016. A copy of the Asia-Pacific Hepatocellular Carcinoma Trials Group (AHCC), National Cancer Centre Singapore, Singapore Clinical Research Institute (SCRI) and Sirtex joint release can be found at this link:

<http://www.prnewswire.com/news-releases/sirvenib-a-major-primary-liver-cancer-study-in-the-asia-pacific-region-completes-enrolment-581948551.html?a>

The AHCC trials group would like to take this opportunity to thank all investigators and study team members who have been involved in this study and worked towards its successful conclusion.

Participating Sites

Brunei

- The Brunei Cancer Centre

Indonesia

- University of Indonesia
- Sanglah General Hospital

Korea

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

Malaysia

- Penang Adventist Hospital
- Sarawak General Hospital
- University Malaya Medical Centre

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

- 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

Thailand

- Chulabhorn Hospital

VESPRO

Patient prospective meta-analysis of Selective Internal Radiation Therapy (SIRT) vs Sorafenib 400mg for advanced, locally advanced or recurrent Hepatocellular Carcinoma (HCC) including SARAH and SIRveNIB trials

Meta-Analysis of the SIRveNIB and SARAH Studies

VESPRO is an investigator-initiated prospective meta-analysis of the SIRveNIB and SARAH Studies jointly collaborated between the AHCC06 Trials Group and the French SARAH study team, Assistance Publique - Hôpitaux de Paris. Both studies share similar protocols designed to compare efficacy and safety of Y90 microspheres versus sorafenib treatment in advanced Hepatocellular Carcinoma. VESPRO will compare overall survival of Y90 microspheres versus sorafenib using the combined datasets from the two studies after final data analysis of individual study is performed. Its primary endpoint of VESPRO is all cause-mortality measured by overall survival.

This is a combined prospective database with both Asian and European populations and it contains potentially important data for Hepatocellular Carcinoma.

It is anticipated that the results of SARAH, SIRveNIB and VESPRO will be published simultaneously in 2017.



SARAH
Sorafenib versus Radioembolization
in Advanced Hepatocellular carcinoma

Asia-Pacific
Hepatocellular Carcinoma
Trials Group

Prof Valérie Vilgrain (Head of Radiology Department, Hospital Beaujon, Coordinating Investigator leading the collaborative group for the SARAH study) and Prof Pierce Chow (Protocol Chair, AHCC06) during a conference in 2013.

AHCC Trials Group Scientific Forum and General Meeting

2016 was a fruitful year for the AHCC Trials Group. The Trials Group has successfully held 2 General Meetings, 8th and 9th General Meeting on 29 January 2016 and 26 August 2016 respectively, 1 Scientific Forum on 29 January 2016 and launched 2 multi-centre studies. Another great milestone achieved for the AHCC Trials Group with the completion of recruitment of the AHCC06 trial in May 2016.

The 3rd Scientific Forum and 8th AHCC Trials Group General Meeting was held on 29 January. Both events were attended by more than 20 overseas investigators. The Scientific Forum was held in the morning and open to the public. More than 150 participant attended the forum at National Cancer Centre. The speakers include Dr Tam Wai Leong, Senior Research Scientist from GIS who presented on Cancer Stem Cells and Heterogeneity, Mr Jonathan Kua, Group Director of A*Star, who shared on the research landscape in Singapore and A/Prof Dan Yock Young, Chair of the University Medicine Cluster, NUHS, who shared on Fatty Liver and HCC. During the Scientific Forum, 2 MOUs were signed. The first MOU is between NCCS and InvitroCue and the second MOU was between NCCS, SCRI and IMS Health. The Scientific Forum ends with a networking lunch.

The AHCC Trials Group members attend the 8th General Meeting in the afternoon. This is a closed-door meeting which prospective studies will be presented and valuable comments from key opinion leaders from Asia Pacific will be discussed.



Picture of Investigators from the AHCC Trials Group and the AHCC06 Study Team members taken during the 8th AHCC Trials Group General Meeting on 29 January 2016.

About 7 months after the 8th AHCC Trials Group General Meeting, the 9th General Meeting was held on 26 August 2016 in conjunction with the AHCC08 Investigators Meeting on 25 August 2016 and AHCC07 Investigators Meeting on 27 August 2016. Since the 8th General Meeting, the AHCC research team has been working with research institutions and partners from industry on possible collaborations on new projects. During the 9th General Meeting, the AHCC Trials Group announced the launch of the new studies, namely AHCC07, Multi-national Cohort Study on the Clinical Trajectory of Resected Hepatocellular Carcinoma (the PLANET study) and AHCC08, HCC Registry in Asia. AHCC07 is funded by an award of the \$7.5 million Translational and Clinical Research (TCR) Flagship Programme grant by the Singapore's National Medical Research Council (NMRC) and the AHCC08 is fully funded by Industry. The General Meeting was attended by more than 30 overseas investigators, with new members from China, Korea, Japan and Thailand. With the initiation of these 2 studies, the size of the trials group has increased to more than 50 members.

The AHCC Trials Group looks forward to the next General Meeting in 2017 and hopes to have more collaborations with research institutions and industry partners.



Picture of Investigators from the AHCC Trials Group and the AHCC06 Study Team members taken during the 9th AHCC Trials Group General Meeting on 26 August 2016.

AHCC07 (PLANET study)

A Multi-national Cohort Study on the Clinical Trajectory of Resected Hepatocellular Carcinoma (HCC)

Precision Medicine in Liver Cancer across an Asia-Pacific Network

Lead PI: Prof Pierce Chow, NCCS, SGH and Duke-NUS

Theme PIs: Dr Zhai Weiwei, GIS

Prof Salvatore Albani, STIIC

Prof Pierce Chow, NCCS



Participating Sites

Malaysia

- University Malaya Medical Centre

Philippines

- The Medical City

Singapore

- National Cancer Centre

- National University Hospital

- Singapore General Hospital

Thailand

- National Cancer Institute Thailand

Members of the AHCC07 study during the Investigators Meeting held in Singapore on 27 August 2016.

The AHCC07 study is one of the projects that have launched under the auspices of the AHCC Trials Group in 2016. It is an international investigator-initiated prospective study which aims to investigate the genomic heterogeneity and immunological profile of surgically resected HCC, and relates them to the subsequent clinical trajectory. Genomic and immunological studies are subsequently repeated when tumours recur, to validate clonally dominant driver mutations and immunological processes that are targetable.

This pivotal study is a collaboration with Genome Institute of Singapore (GIS), SingHealth Translational Immunology and Inflammation Centre (STIIC) and the Cancer Science Institute of Singapore (CSI).

All 6 sites have participated in previous trials under the AHCC trials Group. The study run for 5 years with a sample size of 100 patients. Patients recruited are followed up longitudinally so as to clarify the natural history of HCC. The first patient was recruited in October 2016.

The first AHCC07 Investigators Meeting was held on 27 August 2016 in Singapore and it was attended by all the site investigators and their main study team members.

The project was awarded a S\$7.5 million Translational and Clinical Research (TCR) Flagship Programme grant by the Singapore's National Medical Research Council (NMRC) earlier this year.

AHCC08

Hepatocellular Carcinoma (HCC) Registry in Asia

Protocol Chair: Prof Pierce Chow, NCCS, SGH and Duke-NUS



Members of the AHCC08 study during the Investigators Meeting held in Singapore on 27 August 2016.

Another project for the AHCC Trials Group in 2016 was the AHCC08 study. The HCC Registry in Asia is a first multi-national and multi-ethnic HCC registry that prospectively collects data on the clinical presentation and trajectory, economic burden, management and clinical outcomes of HCC within the Asia-Pacific region. This initiative is a collaboration with National Cancer Centre Singapore (NCCS), Singapore Clinical Research Institute (SCRI) and IMS Health. The longitudinal cohort study will collect real world data from 2,500 patients from 9 countries in Asia Pacific to provide a complete longitudinal picture of the HCC patient journey. This large database could possibly elucidate patterns in liver cancer that could help with developing government policies. As the data available on liver cancer in each country differs, this registry could also help fill in the gaps in specific countries.

This Registry is supported by IMS Health, a leading global information and technology services company specializing in healthcare services. This collaborative effort has also resulted in new outstanding investigators joining the AHCC Trials Group. We are pleased to welcome these investigators into our AHCC network and look forward to working with them on future projects.

The first site, NCCS was initiated on 9 Dec 2016 and the first patient will be recruited early 2017. Recruitment is planned to be completed by the end of 2019.

AHCC Trials Group



(Left) A group picture of the AHCC Trials Group members taken at the Night Safari after the 9th AHCC Trials Group General Meeting on 26 August 2016.

(Right) The study team members of the AHCC07 study having a group after the AHCC07 Investigators Meeting on 27 August 2016.

Since the conception of the AHCC Trials Group in 1997, the AHCC Trials Group Secretariat led by Prof Pierce Chow has been involved in the general administration and management of the AHCC Trials Group network. The Secretariat has been maintaining the network registry, website, social media sites and the publishing of the periodic newsletters for the network to keep the group abreast of any developments and happenings across the network. The Secretariat works closely with academic clinical trials organizations, pharmaceutical and biotech industry partners to organize the General Meetings, Scientific Forums as well as ad-hoc meetings of the trials group.

The AHCC Trials Group will like to thank all the members and collaborators for their support.

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