

AHCC Trials Group

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Contents

1 The Buzz

- New Potential Study to be Initiated Under AHCC Trials Group
- AHCC 01 and AHCC02 Secondary Analysis

2 HCC in Myanmar

- A Special Commentary by Professor Khin Maung Win

3 Highlights – AHCC06

- Study Status
- Initial Site Visits

4-5 Site Initiation Visits



The Principal Investigators

AHCC01 Study:

Prof Jonathan Cebon, *Australia*
Prof Winnie Yeo, *Hong Kong*
Prof Tjakra Wibawa Manuaba, *Indonesia*
Prof Khin Maung Win, *Myanmar*
Prof Michael Findlay, *New Zealand*
Prof Soo Khee Chee, *Singapore*
Prof Pierce Chow, *Singapore*
A/Prof Tan Chee Kiat, *Singapore*
Prof Si-Hyun Bae, *South Korea*
Prof Thiravud Khuaprema, *Thailand*

AHCC02 Study:

Prof Khin Maung Win, *Myanmar*
Prof Michael Findlay, *New Zealand*
Dr Rolley Rey Lobo, *Philippines*
Prof Soo Khee Chee, *Singapore*
Prof Pierce Chow, *Singapore*
Prof Jin-Mo Yang, *South Korea*
Prof Hoang Hoa Hai, *Vietnam*
Prof Nguyen Ba Duc, *Vietnam*

The Buzz...



New Potential Study To Be Initiated Under AHCC TRIALS GROUP!

A new multi-center, investigator-initiated trial is in the pipeline for the AHCC Trials Group. The AHCC Network Secretariat was involved in organising the 1st Steering Committee meeting of the potential study which was held in Singapore, 12th November 2010. Progressing swiftly, the 2nd Steering Committee meeting was recently held in Thailand, Bangkok, 20th February 2011, where the Steering Committee members had fruitful discussions on the protocol. We await further developments of this potential new trial!

AHCC01 and AHCC02 Secondary Analysis

The AHCC Trials Group and the Biostatistics Department of the Singapore Clinical Research Institute will be conducting Secondary data analysis for **AHCC01: High-Dose Tamoxifen in the Treatment of Inoperable Hepatocellular Carcinoma: A Multicenter Randomized Controlled** and **AHCC02: Randomised Double Blind Trial of Megestrol Acetate vs. Placebo in Treatment-Naïve Advanced Hepatocellular Carcinoma**. The analysis will be based on the pooled data from the above mentioned trials to look at the following topics:

- 1) Improve our understanding of the measurement properties and interpretation of Global Quality of Life and other scale scores of the European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire. In addition, to assess the equivalence/comparability of the difference language version as well as different modes of administration.
- 2) To assess and compare the natural history and survival of patients across countries and ethnic groups, and examine prognosis according to Okuda stage
- 3) To evaluate the performance of approaches to Quality-adjusted lifetime (QAL) estimation by comparing the known truth and results based on data with censoring imposed, and to use the anonymised data for exploration and illustration of QAL methods.



Prof. Khin Maung Win

Consultant Hepatologist
& Principal Investigator

Yangon GI & Liver
Centre, Myanmar



..almost all inoperable HCC patients received only symptomatic treatment or systemic chemotherapeutic agents of no proven efficacy.



A Special Commentary on HCC in Myanmar

By Prof. Khin Maung Win

Hepatocellular Carcinoma (HCC) is one of the top ten highest causes of death in Myanmar. WHO has also categorized Myanmar as one of the countries of highest incidence of HCC.

Blood screening program for Hepatitis B and C were introduced in Myanmar only 20 years ago. Hepatitis B vaccination was included in the national vaccination programme only in 2006 with the funding from Melinda Gate foundation.

Aetiology and Clinical Presentation

Hepatitis B and C carrier rates in the general population is 10% and 4% respectively and almost all the cases of HCC in Myanmar are caused by either Hepatitis B or C. Anti-viral therapies for Chronic Hepatitis B and C viz; injecting pegylated interferon and oral nucleoside analogues are available in Myanmar. However the prices of these antiviral are prohibitively expensive for the majority of the patients.

Moreover, there is no proper screening programme for the early detection of HCC among the Chronic Hepatitis B and C patients. Therefore, HCC is quite common in Myanmar and usually presents in the advanced stage. Less than 5% of the HCC patients are resectable.

Treatment Options for Inoperable HCC Patients in Myanmar

Treatment options for inoperable HCC patients in Myanmar are very limited. Radio Frequency Ablation therapy is not available. TACE can be done only in two centres in the whole of Myanmar and is not accessible to majority of the HCC patients. Sorafenib is not available as well.

In general, because of the lack of specific treatment modalities, almost all inoperable HCC patients received only symptomatic treatment or systemic chemotherapeutic agents of no proven efficacy.

As Yangon GI and Liver Centre participated in the AHCC 01 and AHCC 02, and is still participating in AHCC 05 and AHCC 06 studies, fortunate patients recruited in these studies got a chance to be treated with the trial treatment regime.

Summary and Conclusion

In summary, Myanmar needs effective Hepatitis B vaccination programme for newborns and expanded vaccination for the whole country to prevent HCC. In Myanmar, most of the HCC cases are seen in advanced and inoperable stage and no treatment can be offered. Proper HCC screening programme should also be set up to detect early HCC in resectable stage. Treatment for the inoperable HCC patients such as TACE or Y90 radio-embolisation should be introduced and expanded in Myanmar.

Recommendation

It is presumed that the HCC situation in developing countries in Asia will be more or less the same in Myanmar in a sense that the clinicians will be facing a huge population of inoperable HCC cases without having any effective treatment plan available.

Therefore, it is entirely essential to conduct clinical trials to develop novel therapeutic regimes for advanced HCC and it is desirable that the priority of clinical trials should be given to those which are appropriate and relevant to the Asia Pacific region.

Highlights



The SIRveNIB Trial

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, Singapore General Hospital (Department of General Surgery)

Study Status:

As the trial progresses, the year of 2011 kickstarted with the site initiation of Cipto Mangunkusumo Hospital, Indonesia on Feb 23rd 2011. Following that, National Cancer Center of Mongolia was initiated on 1st and 2nd March 2011. The team at Changi General Hospital, Singapore had undergone retraining of the trial's latest developments in protocol and work processes on 9th March 2011 and is now ready for recruitment. Subsequently, The Medical City, Philippines was initiated on 4th and 5th April 2011. The latest center initiated was Khoo Teck Puat Hospital, Singapore which opened for recruitment on 13th April 2011.

As of today, there are 24 participating sites from 11 countries. 10 sites (5 local, 5 overseas) have been initiated and are currently recruiting. Recruitment results have been encouraging. A total of 49 patients are enrolled into the trial with 23 patients randomized to the SIR-Spheres treatment and 26 patients to the Sorafenib treatment arm. With more sites coming onboard, we look forward to a higher recruitment number this year!

Initial Site Visits!

Queen Mary Hospital



Prof Pierce Chow (SGH) together with Ms Cynthia Lee (SCRI), Ms Peggy Yong (Sirtex), Prof Ronnie Poon (center) and his team.

Towards the end of January, the study team visited Prof Ronnie Poon and his team at Queen Mary Hospital, Hong Kong. During the visit, the team were given a tour around the hospital and gained an overview of the general set-up of the hospital. Being the key center for HCC surgery, Queen Mary Hospital receives the highest number of HCC cases in Hong Kong.

ALERT

The AHCC06 Trial Recruitment Website is up! Visit it at : <http://www.sirvenib.com/>

Centers Open for Recruitment:

Indonesia:

Cipto Mangunkusumo Hospital

Mongolia:

National Cancer Center of Mongolia

Myanmar:

Yangon GI & Liver Centre

New Zealand:

Auckland City Hospital

Philippines:

The Medical City

Singapore:

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

Site Initiation Visits!

Cipto Mangunkusumo Hospital

Cipto Mangunkusumo Hospital, Indonesia is an established medical institution which has the availability of a huge HCC patient pool. The hospital was initiated on Feb 23rd 2011 and it is the first collaboration between the site and the AHCC Trials Group. Prof L.A Lesmana and his team were very eager about the trial and showed a lot of interest in understanding the study during the training sessions. In addition, the SCRI team found the research facilities to be adequate for the trial. Overall it was a good experience for the team.



Left: Ms Cynthia Lee (SCRI), Prof L.A Lesmana (CMH), Prof Pierce Chow (SGH), Ms Pritha Bhadra (SCRI)

A First for National Cancer Center of Mongolia and SCRI



It is the first time that the AHCC Trials Group opened a center in Mongolia and it was quite an adventure for the study team who had never been to Mongolia before. In November last year, the team braved the cold weather of -30 degree Celsius for their initial site visit to National Cancer Center to meet up with Dr Ariunaa and her team. During the site evaluation exercise, the National Cancer Center was found to be well-equipped with facilities for the treatment of cancer patients. As this is the first time that the Mongolian center is participating in a clinical trial, the team from SCRI was generally impressed by the standard of the research facilities there.

On 1st March 2011, the team travelled to the institution again for site initiation. During the 2 days of site initiation, there were fruitful dialogues between the two teams which they had extensive exchanges to establish the trial processes and logistics. The 2 days of hard work was followed by a great feast. As this is a pioneering project for the teams from both countries, we are eager for this collaboration to be a success.



Bottom: Dr Ariunaa Khasbazar (Center) and her team together with Prof Pierce Chow and the SCRI study team

Announcement:

Priscilla will be on maternity leave for the coming months. We would like to extend our congratulations to Priscilla for the blessed gift that she will receive soon!!



Calling Out to All!

If you are thinking about a new study concept and wish to collaborate with us, do contact the Network Secretariat for more information. Contact details can be found on this newsletter.

Asia-Pacific
Hepatocellular Carcinoma
Trials Group

Group Chair: Prof Soo Khee Chee
Protocol Chair: Prof Pierce Chow

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

Trial Coordinating Centre:



Website: <http://www.scri.edu.sg/>

Contact Details of the Network Secretariat:

Ms Priscilla Li
priscilla.li@scri.edu.sg
Contact No. (Office):
(65)6508 8357
Fax No:
(65)6508 8317

Ms Chan Wai Ming
waiming.chan@scri.edu.sg
Contact No. (Office):
(65)6508 8314
Fax No:
(65)6508 8317

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

The Medical City



Left: Prof Pierce Chow (SGH) presenting to Dr Janus Ong and his team (TMC)

The site CRA for The Medical City in the Philippines, Ms Pritha Bhadra, commented after her visit:

"The Site Initiation Visit at "The Medical City" was held on 4th & 5th April 2011 with Dr. Janus Ong (Site PI) and his team. We had the Protocol presentation by Prof Pierce Chow and presentation on the Study Operations and Logistics by the SCRI team members. Dr. Janus and his team were very friendly to us during our visit; we had lunch together on the 4th. The SIRTEx representatives from the Philippines and Singapore were also present during our visit and were very helpful with the logistics. This was my first visit to the Philippines and the people's hospitality gave me a very good impression. I look forward to my next monitoring visit to the Philippines in the coming months."

Khoo Teck Puat Hospital

The site CRA for Khoo Teck Puat Hospital in Singapore, Ms Samantha Chow, reports:

"The Site Initiation Visit (SIV) for Khoo Teck Puat Hospital (KTPH) was held on 13th April 2011. It had been a challenging journey to get KTPH to join us and we are very delighted and privileged to finally have them in the AHCC06 family. The SIV was smooth and successful and all of us (CRAs) had an enjoyable sharing session with the team. Together with us at the SIV was our protocol chair, Prof. Pierce Chow and Sirtex representatives Ms. Peggy Yong and Mr. William Kow. We toured this newly-built hospital and were very impressed by its architecture and facilities. Through our conversation with the PI, Dr. Jude Lee, we also realised that he is a passionate clinician who is constantly thinking of helping his patients to lessen the burden of their illnesses on them. With his enthusiasm and his team of very experienced coordinators and pharmacists, we strongly believe that KTPH will be able to contribute significantly in this trial."

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