

ADD PROJECT TO THE KIRBY INSTITUTE WEBSITE – ATAHC II

Section1 – In the top box

Title: Treatment of recently acquired hepatitis C virus infection (ATAHC II)

Tags: Hepatitis C treatment, recently acquired hepatitis C virus infection, response-guided therapy, individualized therapy, IDUs

Date Commenced: July 2010

Date Completed: April 2015

Project Funding: US National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA)

Currently Recruiting (Yes/No): No

Photo: logo or other photo (place in the P:\NCHECR\Website\Projects\Images folder)

Section2 – About the project

Rational: In chronic hepatitis C therapeutic management, treatment is increasingly individualised. Duration of therapy is based on an individual's early virological response to treatment and the timing of when an individual's HCV RNA first becomes undetectable. Such 'response guided therapy' has the potential to minimise cost and toxicity issues whilst maintaining virological efficacy. In the ATAHC II the strategy of response guided therapy in acute and recently acquired HCV infection will be evaluated.

Aims: The main aim of the study is to identify the optimal therapeutic strategy for patients with recently acquired hepatitis C virus (HCV) infection.

Design & Method: Eligible subjects will be offered open-label HCV treatment with Peginterferon with or without Ribavirin, depending on their HIV status and their duration of HCV infection. The duration of treatment will be guided by the subject's virological response to treatment and will range from 8 weeks to 48 weeks (e.g. subjects with a very rapid virological response – undetectable HCV RNA at week 2 – will receive 8 weeks and those with a rapid virological response – undetectable HCV RNA will receive 16 weeks). Subjects who are not eligible or choose to remain untreated will be monitored for up to 2 years. Subjects who have very recently acquired HCV (within the last 12 weeks of screening) will be eligible to participate in the early acute HCV infection substudy. In the substudy, subjects will attend additional visits between screening and baseline to be monitored closely for HCV spontaneous clearance.

Progress: There are nine study sites participating in the Study. The sites are St. Vincent's Hospital, Sydney, Royal Prince Alfred Hospital, Kirketon Road Centre and Nepean Hospital in NSW, The Alfred Hospital, Royal Melbourne Hospital and St. Vincent's Hospital, Melbourne in VIC, Royal Adelaide Hospital in SA and Princess Alexandra Hospital in QLD. NSW sites have received ethics approval. VIC sites to submit to ethics in June for the meeting in July 2011. Both SA and QLD sites have submitted to ethics.

Benefits: The potential benefit of improving treatment outcomes for patients with recently acquired hepatitis C virus infection.

Output: N/A

Section 3 – Contributors

Program/s: Viral Hepatitis Clinical Research Program

Project members: Prof. Greg Dore (NIH grant Principal Investigator, Study Co-Chief Investigator), Dr Gail Matthews (ATAHC II Study Principal Investigator), Prof. John Kaldor (co-investigator), Barbara Yeung (Project Coordinator), Pip Marks (Clinical Trials Manager), Dr Jason Grebely (co-investigator), Dr Tanya Applegate (co-investigator), Dr Kathy Petoumenos (co-investigator), Ineke Shaw (System Manager), Sharmilla Siriragavan (Data Manager).

Other investigators: A/Prof. Margaret Hellard (co-investigator, the Burnet Institute), A/Prof. David Shaw (co-investigator, Royal Adelaide Hospital), Prof. Paul Haber (co-investigator, Royal Prince Alfred Hospital), Prof. Andrew Lloyd (co-investigator, UNSW), Dr Alex Thompson (co-investigator, St. Vincent's Hospital,

VIC), Dr David Iser (co-investigator, St. Vincent's Hospital and the Alfred Hospital, VIC), Dr Joe Sasadeusz (co-investigator, Royal Melbourne Hospital), A/Prof. Silvana Gaudieri (co-investigator, Royal Perth Hospital and Murdoch University, WA).

Collaborating centres:

- St. Vincent's Hospital, Sydney, NSW
- Kirketon Road Centre, Sydney, NSW
- Royal Prince Alfred Hospital, Sydney, NSW
- Nepean Hospital, Sydney, NSW
- The Alfred Hospital, Melbourne, VIC
- Royal Melbourne Hospital, Melbourne, VIC
- St. Vincent's Hospital, Melbourne, VIC
- Royal Adelaide Hospital, Adelaide, SA
- Princess Alexandra Hospital, Brisbane, QLD

Section 4 – Publications related to this project

No need to fill out as this will automatically populate from the filtered publication database for that project.

RIGHT SIDE MENU OPTION

Section 1 – Menu

No input needed.

Section 2 – Project contacts

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