



Media release for World Hepatitis Day/Hepatitis Awareness Week

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Good news about hep C treatment for people with haemophilia

Results presented at an international conference have given hope of a cure for those people in Australia with bleeding disorders who also live with hepatitis C.

For people living with long-term infection with hepatitis C, the results of clinical trials of hepatitis C treatment presented at the European Association for the Study of the Liver (EASL) Congress in Copenhagen at the end of April 2009 give welcome news of higher cure rates. This is even for those with genotype 1, the commonest strain of hepatitis C among people with bleeding disorders in Australia, but also the hardest to treat.

“Many people with haemophilia in Australia acquired hepatitis C from the blood products they used for treatment in the days before testing was available for the virus,” explains Gavin Finkelstein, Haemophilia Foundation Australia President. “That means they’ve been living with hepatitis C for 20-30 years, with symptoms such as fatigue, nausea and liver pain – and that’s on top of the joint damage and other effects of repeated bleeds from the haemophilia itself.”

“We think I was actually infected way back in 1978, when I started treatment with a plasma concentrate pooled from many donors,” says Kevin Fisher, who has haemophilia, “but I didn’t find out until 1990 after hepatitis C testing became available. Back then I was told by a specialist that I probably only had 20 years ahead of me because there was no treatment at that stage. I had a responsible job in a major Australian company and the hep C symptoms made it hard to do my work – I had to give up my social life and looking after things at home and slept all weekend, just so that I could go back into work on Monday.”

“The concern for those who have this liver infection is the possibility of serious liver damage or liver failure over time – including those with bleeding disorders who have long-term infection, which can increase the risk of liver damage,” explains Associate Professor Stuart Roberts, Director, Gastroenterology and Hepatology at The Alfred hospital in Melbourne. “The good news is that the results of treatment continue to improve – and successful treatment can prevent liver failure.”

“You know, I’d got used to the idea that I was only going to live a short life, which was confirmed for me when I tried hepatitis C treatment in the early 90s. It had some difficult side effects and didn’t help,” says Kevin Fisher. “But last year I decided to have the latest therapy and although it had side effects too, it’s been successful and I’ve cleared the hepatitis C virus. I’d given up hope but now I feel better than I have for years. My wife and I have just had our first real holiday in several years and it’s been great.”

According to the results of the large Australian led, international CHARIOT clinical trial presented at the European Association for the Study of the Liver Congress in Copenhagen at the end of April 2009, people with genotype 1 hepatitis C who receive treatment when they have minimal, or no liver damage, have double the chance of a cure, compared to those treated in the later stages of liver disease. The study included more than 700 Australians with hepatitis C and 33 Australian hospitals.

“These cure rates are a lot higher than we thought – up to 7 out of 10 people with genotype 1 may be cured if treatment starts before liver scarring or damage has occurred,” says Stuart Roberts, who was the lead investigator.

And it's far from hopeless for people who already have some liver damage or who previously relapsed after treatment. Some, like Kevin, have recently had successful treatment or retreatment with the current standard treatment.

The same international conference also reported on the new hepatitis C treatments in the pipeline. A combination treatment of a new drug telaprevir with pegylated interferon and ribavirin is currently being trialled in Australia. At the conference, researchers presented data on the US/European arm studying people with genotype 1 hepatitis C treated with this triple therapy. The study found that up to 76% people who had previously relapsed achieved a cure with this treatment.

“This new treatment combination shows great promise for people with bleeding disorders who relapsed following previous treatment,” says Stuart Roberts.

If the clinical trials continue to show successful results the treatment should be available in Australian clinics some time after 2010.

“There could be over a thousand people with bleeding disorders in Australia who acquired hepatitis C via blood products contaminated with hepatitis C ” claims Gavin Finkelstein. “Some of them have already cleared hepatitis C naturally or through treatment. But for the many others who haven't been so fortunate, we encourage them to come forward, have their liver health reviewed and talk to their hepatitis specialist about their options for hep C treatment - we know it won't help everyone, but it's worth knowing where you stand. Life is tough enough with haemophilia without having to battle with hep C as well.”

BACKGROUND

Inherited bleeding disorders include haemophilia and von Willebrand Disorder and other rare factor deficiencies. There are approximately 3600 people diagnosed with inherited bleeding disorders in Australia.

Haemophilia

Haemophilia is a rare inherited bleeding disorder. Haemophilia occurs when blood clotting factors VIII (eight) or IX (nine) are missing in a person's blood or don't work properly. It is not curable and can be life threatening if not treated properly. Bleeding is mostly internal into muscles and joints. Over time it can cause damage to muscles and joints, resulting in pain, disability and reduced quality of life.

Haemophilia is an inherited condition and occurs in families. However, however in 1/3 of cases it appears in families with no previous history of the disorder. The haemophilia gene is passed down from parent to child through generations. Men with haemophilia will pass the gene on to their daughters but not their sons. Women who carry the haemophilia gene can pass the haemophilia gene on to their sons and daughters. Sons with the gene will have haemophilia. Although women can carry the gene, only very rarely do they have haemophilia. However, some may also experience bleeding problems. Haemophilia is found in all races and socio-economic groups – the most famous woman to carry the gene was Queen Victoria of England.

With appropriate treatment bleeding can usually be stopped. Young people who have been treated all their lives with clotting factor are likely to live a normal life. Unfortunately older people with bleeding disorders may not have had access to optimal amounts of clotting factor and may live with the long term effects of chronic bleeding and blood borne viruses. Treatment is with replacement clotting factor treatments injected intravenously up to 2-3 times every week. Blood clotting factor products are produced from either human

blood plasma or 'recombinant' or synthetic product manufactured commercially in laboratories. Most people with haemophilia in Australia now use recombinant products as a safety precaution.

Von Willebrand disorder

Von Willebrand disorder (vWD) is another inherited bleeding disorder caused when there is not enough of the von Willebrand clotting factor in a person's blood, or it doesn't work properly. It is thought that many Australians with vWD are undiagnosed as it is more common in a mild form, and most people do not need treatment unless they have surgery or an injury. However, some people have severe vWD with frequent bleeding episodes and joint and muscle bleeds. Some people with vWD can only be treated with clotting factor VIII concentrates made from human plasma, while others can be treated with synthetic hormones.

Hepatitis C and clotting factor plasma concentrate

In Australia more than a thousand people with bleeding disorders treated with clotting factor concentrates produced from human plasma are thought to have been infected with hepatitis C virus (HCV) and/or HIV through treatment products before viral inactivation processes were introduced and HCV antibody testing began in 1990. Some have since died and others have significant liver disease caused by 20-30 years of hepatitis C infection.

Clotting factor plasma concentrates are usually pooled from the blood of thousands of donors and at that time only needed one donation with HCV to infect a batch. Blood product safety precautions in Australia now ensure that blood products are as safe as possible from blood borne viruses such as HCV: donors are screened, donations are tested for HCV and human plasma factor concentrates are treated with several viral inactivation processes. Most people with haemophilia are now treated with recombinant clotting factor, which is genetically engineered and contains little or no human or animal material. There have been no reports that viruses have been transmitted by recombinant products.

Hepatitis C

Hepatitis C is caused by a virus, hepatitis C virus (HCV), that can lead to liver inflammation and liver disease. Hepatitis C is spread through blood-to-blood contact. It is a slow-acting virus and for most people does not result in serious disease or death. Approximately 260,000 Australians have been exposed to the hepatitis C virus. There is currently no vaccination.

In Australia, the current standard treatment is pegylated interferon and ribavirin, which helps the immune system and attacks the virus. The aim of treatment is a "sustained viral response (SVR)", or clearance of HCV from the blood, and is considered a cure. Some people with bleeding disorders have had unsuccessful treatment in the past with less effective treatments, such as interferon monotherapy. Retreatment with the current standard treatment has shown some limited success and became available under the government subsidised Pharmaceutical Benefits Scheme in December 2008.

The results of several important clinical trials of hepatitis C treatment were presented at the European Association for the Study of the Liver (EASL) Congress in Copenhagen, April 22-26 2009.

- The Australian-led CHARIOT study involved more than 700 Australians with genotype 1 hepatitis C, the most common and most difficult to treat strain of infection. These patients had not had treatment before. The study was led by Associate Professor Stuart Roberts, Director of Gastroenterology and Hepatology, The Alfred hospital, Melbourne. The study was sponsored by Roche Products Pty Ltd.
- The PROVE3 study investigated the results of a new treatment combination which included a third drug telaprevir, to the combination of pegylated interferon and ribavirin. The study included 453 genotype 1 hepatitis C patients in the US and Europe who had previously had unsuccessful treatment. Telaprevir is currently being trialled in Australia under the sponsorship of Tibotec Pharmaceuticals Ltd and Vertex Pharmaceuticals Inc.

Data on people with bleeding disorders and hepatitis C has been collected for the Australian Bleeding Disorders Registry but is not yet available. Overseas studies suggest that without treatment, of every 100 people with bleeding disorders infected with hepatitis C, about 20 will get rid of the virus themselves within

two to six months, but will continue to have the signs of past infection through hepatitis C antibodies in their bodies. That means about 80 of the 100 people will develop ongoing (or chronic) infection. About 16 of these will develop cirrhosis, and a smaller number will develop liver failure or liver cancer after 20 to 30 years of infection. Many may experience symptoms such as liver pain, nausea, fatigue, depression and 'brain fog'. Others may be well and have no symptoms.

Treatment can prevent this sequence of events, especially if given before liver damage has occurred.

Hepatitis Awareness Week (18-24 May 2009)

The theme for World Hepatitis Day, celebrated globally on May 19, is "Am I number 12? 1 in 12 people worldwide have hepatitis B or hepatitis C" - www.aminumber12.org. Haemophilia Foundation Australia (HFA)'s national theme for Hepatitis Awareness Week is "I am number 12: I'm part of a world community with hepatitis C, but this is my story". Fact sheets on disclosure and personal stories will be launched from the HFA web site on May 19 – www.haemophilia.org.au

The Haemophilia Foundation

Haemophilia Foundation Australia (HFA) represents people with haemophilia, von Willebrand disorder and other related bleeding disorders and their families. HFA is committed to improving treatment and care through representation and advocacy, education and the promotion of research. HFA supports a network of State and Territory Foundations in Australia.

As a National Member Organisation of the World Federation of Hemophilia, HFA participates in international efforts to improve access to care and treatment for people with bleeding disorders around the world.

www.haemophilia.org.au

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