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Hepatitis C: Ribavirin/Pegylated Interferon combination therapy

Introduction

This information sheet is for people who want to know more about the ribavirin/pegylated interferon combination treatment for Hepatitis C (HCV). There are currently new treatments for HCV starting to be used in conjunction with interferon treatment. Please see the ERC "Tests and treatments" Fact Sheet for more information on these newer treatments. This Fact Sheet will only focus on ribavirin/pegylated interferon combination therapy

What the treatment does

The aim of the treatment is to clear the hepatitis C virus from your blood and go from PCR positive to PCR negative. This is referred to as a sustained virological response (SVR). Taking ribavirin and pegylated interferon together is currently the standard of care treatment for hepatitis C (SOC). This is also commonly known as "combination therapy".

Am I eligible for combination therapy?

To receive pegylated interferon and ribavirin combination therapy under the government subsidised scheme (S100) you need to meet the following criteria:

- a positive hepatitis C antibody test
- a positive hepatitis C PCR test
- not be pregnant or breastfeeding
- for men your partner must not become pregnant while you are on treatment and for six months after treatment has ceased
- use contraception with bith partners taking precautions to prevent pregnancy





People who inject drugs and/or use methadone and people co-infected with HIV are eligible for combination therapy. You cannot be refused treatment because you continue to inject drugs. This would need to be discussed with your specialist doctor or nurse. If you do currently use alcohol or drugs then you can access the integrated health care hepatitis treatment service (IHCS) clinics that currently run within the state of Victoria. Contact Hepatitis Victoria on the details given below to find out the nearest IHCS clinic to you. The Alfred Hospital run IHCS clinics in St Kilda, Collingwood and Frankston.

Hepatitis C genotypes 1, 4, 5 and 6

People with genotype (strain) 1, 4, 5 or 6 who are eligible for 48 weeks of treatment may only continue treatment after the first 12 weeks if the result of a PCR test shows that the virus has become undetectable or the viral load has decreased (measured by at least a 2 log drop – a 2 log frop measn that 2 zeros are knocked off the viral load measurement).

People with genotype (strain) 1, 4, 5 or 6 who are PCR positive at week 12 but have attained at least a 2 log drop in viral load may only continue treatment after 24 weeks if HCV is not detectable by a PCR test at week 24.

These parameters have been put in place because research has shown that if the virus level has not dropped by weeks 12 or 24 then you will not clear the virus.

Hepatitis C genotypes 2 and 3

People with genotype 2 or 3 generally require 24 weeks of therapy with combination pegylated interferon and ribavirin, People with genotype 2 or 3 with cirrhosis or bridging fibrosis (the stage of liver damage before cirrhosis) may only continue treatment after 24 weeks if HCV is not detectable by a PCR test at week 24. PCR tests at week 24 are unnecessary for people with genotype 1,4,5 or 6 who test negative at week 12.

Your specialist doctor or nurse will also obtain a hepatitic C viral load blood test at the start of treatment and a hepatitis C PCR test at treatment week 4. These are important tests that give an early indication as to how responsive your virus is to the treatment.







What is Ribavirin?

Ribavirin is a tablet taken twice a day with food as part of combination HCV treatment. Ribavirin helps reduce the ability of the hepatitis C virus to replicate and improves the chance of clearing HCV.

What is Pegylated Interferon?

Pegylated interferon is a long-acting form of interferon which fights viral infections. It is made when a chemical called polyethylene glycol (PEG) is attached to interferon. PEG helps the interferon to work in your body for longer. It is given once a week as an injection just under the skin.

What other tests do I need to have before I start treatment?

Fibroscan

There is no longer a mandatory need for a liver biopsy. This has been replaced by Fibroscan which is a device to measure the elasticity or "stiffness" of the liver. The amount of liver stiffness will normally indicate whether you have minimal, moderate or severe scarring at the time of the scan.

If the results of the Fibroscan show that you have cirrhosis your doctor would need to be more cautious when considering treatment for your hepatitis C. You would need to work closely with your specialist doctor and nurse and may need to take the treatment for a longer period of time. You would need to attend your appointments regularly to ensure the safety and efficacy of any prescribed treatment.

IL28B

There is a further blood test that can be taken at your specialist clinic called an IL28B test. This test gives an indication as to how well you may respond to the treatment. There are three possible results (CC, CT and TT) and these would be discussed with your specialist.

Responding to treatment

People who start treatment will be monitored to see how well the treatment is working and how they are responding to treatment. There are a number of different strains (genotypes) of HCV which respond differently to treatment.





Some people are also more likely to clear the virus than others. These are people who:

- have genotype 2 or 3 of the virus
- have lower levels of virus in their blood before they start taking the treatments
- have minimal or no evidence of fibrosis (scarring) in their liver
- IL28B result CC for genotype 1
- are 40 years old or younger when they got the hepatitis C virus
- are female

Side effects

Side effects vary from person to person however most people have some side effects when they take ribavirin and pegylated interferon. One person could have a number of side-effects and another might have very few or only mild side effects. It is important to contact your liver clinic if you have any concerns whilst undergoing treatment.

Side-effects of Pegylated Interferon

Some common side-effects with pegylated interferon are:

- feeling like you have the flu, such as headaches, muscle aches, joint aches, fevers/chills and feeling sick
- vomiting, loss of appetite, diarrhoea
- dry skin, dry eyes, dry mouth, hair loss
- less energy, feeling tired, difficulty sleeping
- depression, mood swings, poor concentration, vagueness
- some people also have changes in their blood such as less white blood cells and platelets (clotting blood cells) and thyroid problems

Most of these side-effects are not serious and will go away over time once you stop taking the treatments. Some people have found that by taking interferon at night, they sleep through the flu-like symptoms.

Side-effects of Ribavirin

Ribavirin may cause anaemia (a low number of red blood cells in the blood). Anaemia can cause shortness of breath, light headedness and tiredness. If this happens talk to your doctor as the amount of ribavirin may need to be changed.

Studies have found that ribavirin may cause birth defects which is why it is essential that both women and men taking ribavirin need to use effective birth control while they taking the treatments and for six months





afterwards. Men need to use condoms during sex as ribavirin has been found in semen. People who have heart or lung disease or who are over 60 years old may need to have extra tests before taking ribavirin or may not be able to take it at all.

Lifestyle issues

If you are interested in treatment, then it is important to think about how it may affect your lifestyle and relationships. Some people find that the side effects of treatment affect their ability to work. You may need to take time off work or talk to your manager about changing your working hours while you are on treatment.

Many people find it helps to talk about the treatments and their potential side effects with the important people in their life. If side effects do occur, then partners, family and friends feel better prepared to provide support. You may wish to bring them along to the appointments so they can get more information and have a greater understanding of what you are going through once you start treatment.

If you are thinking about having children you may choose to have a baby and then start the treatments. Or you might choose to take the treatments, and then wait for six months after you have finished before thinking about having a baby.

Thinking about these issues and talking with your doctor is an important part of preparing for treatment. You may also want to talk with a counsellor. For contact details of a hepatitis C counsellor call Hepatitis Victoria (see details below).

Availability of treatment

If you are interested in accessing treatment you need to see your GP and have some blood tests ordered and obtain a referral to see a Hepatologist (Liver specialist) or specialist nurse. You will have the opportunity at this appointment to ask about what the treatment might mean for you.







Latest research

There are newer treatments for hepatitis C known as Directly Acting Antivirals (DAA's). These are currently only available on a clinical trial basis via referral to a tertiary centre registered to conduct trials (most commonly one of the major public hospitals). It is important to note that the DAA treatments are in addition to the current Ribavirin and Pegylated Interferon treatment, known as standard of care (SOC). Talk with your doctor or specialist nurse about DAAs.

Useful contacts

Hepatitis Australia – www.hepatitisaustralia.com

Hepatitis Victoria – <u>www.hepcvic.org.au</u>

Hepatitis Victoria info line – 1800 703 003 9.30am – 6.00pm - Monday – Friday

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