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<b>STUDY TITLE:</b>	<p><b>A Phase IV, Randomised, Multicentre, Efficacy and Safety Study Examining the Effect of Induction Dosing with the combination of peginterferon Alfa-2a and Ribavirin in Patients with Chronic Hepatitis C Infected with Hepatitis C Genotype 1</b></p> <p><b>Protocol No: ML17908</b></p>
<b>STUDY OBJECTIVE:</b>	<p>The purpose of the study is to compare the effectiveness of two treatment regimens in reducing or clearing the Hepatitis C Virus in patients infected with Hepatitis C genotype 1.</p>
<b>STUDY DESIGN:</b>	<p>If you are eligible to enter the study, you will randomised to receive one of the two possible treatments:</p> <p>A. <b>Treatment Group A</b> = Induction dose: You will receive Pegasys 1 x 360µg subcutaneous injection /week plus ribavirin (5-6 tablets/day) for 12 weeks followed by Pegasys 1 x 180µg subcutaneous injection /week plus ribavirin (5-6 tablets/day) for 36 weeks. The total treatment period is 48 weeks.</p> <p>B. <b>Treatment Group B</b> = standard dose: You will receive Pegasys 1 x 180µg subcutaneous injection /week plus ribavirin (5-6 tablets/day) for 48 weeks.</p>
<b>STUDY DRUGS:</b>	<p>Pegasys (Peginterferon alfa-2a) + Ribavirin</p>
<b>STUDY COMPLETION DATE:</b>	<p>Recruitment stop date: June 2006 Study closure date: July 2007</p>
<b>IS THE STUDY OPEN TO ENROLLMENT?:</b>	<p>Yes</p> <p>To enter the study you must be an adult infected with hepatitis C virus, genotype 1 confirmed by a positive hepatitis C virus test, and a liver biopsy performed within the last 18 months.</p> <p>If you have a history of another severe or serious illness which would interfere with your participation, you will be unable to participate in the study. This is for your safety, since these conditions could get worse on treatment.</p>
<b>NUMBER OF PATIENTS ENROLLED/TARGET ENROLLMENT:</b>	<p>67 participants currently enrolled with an aim to recruit 816</p>
<b>SPONSOR:</b>	<p>F Hoffmann-La Roche Ltd./Inc/AG/ Roche Global Business and National Centre In HIV Epidemiology and Clinical Research (NCHECR) at University of New South Wales</p>
<b>PARTICIPATING SITES:</b>	<p><b>ACT:</b> Canberra Hospital</p> <p><b>NSW:</b> Albion Street Clinic, St Vincents Hospital, St George</p>

	<p>Hospital, Westmead Hospital, Liverpool Hospital, Bankstown Hospital, Liverpool Sexual Health Clinic, Nepean Hospital, John Hunter Hospital, Wollongong Hospital, Royal Prince Alfred Hospital, Concord Hospital</p> <p><b>VIC:</b> Monash Medical Centre, St Vincents Hospital, The Alfred Hospital, Royal Melbourne Hospital, Western Hospital, Geelong Hospital, Box Hill Hospital, Austin Hospital</p> <p><b>QLD:</b> Princess Alexandra Hospital, Nambour Hospital, Royal Brisbane Hospital, Townsville General Hospital</p> <p><b>SA:</b> Royal Adelaide Hospital, Flinders Medical Centre</p> <p><b>WA:</b> Sir Charles Gairdner Hospital, Fremantle Hospital, Royal Perth Hospital</p> <p><b>TAS:</b> Royal Hobart Hospital</p>
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