HALT-C Trial

Trial Ineligibility

Form # 5 Version B: 12/03/2001

SECTION A: GENERAL INFORMATION

A1. Affix ID Label Here → __ __ - __ __ __ - __

A2. Patient initials: __ __ __

A3. Visit number: S 0 0

A4. Date form was completed: MM / DD / YYYY __ __ / __ __ / __ __ __ __

A5. Initials of person completing form: __ __ __

SECTION B: REASON FOR TRIAL INELIGIBILITY

Please select the reason(s) why the patient is ineligible: (Choose up to four reasons from the list below.)

B1	B2	B3	B4
__ __	__ __	__ __	__ __
If ans = 99, specify: _____	If ans = 99, specify: _____	If ans = 99, specify: _____	If ans = 99, specify: _____

Ineligibility Reason Codes

1. Age < 18 years
2. HCV Serology negative
3. Previous IFN treatment dose or duration insufficient
4. Previous IFN treatment response
5. HCV RNA negative by Core Virology Lab
7. Liver biopsy – biopsy does not meet entry criteria
8. Not willing to use adequate contraception
9. Hepatitis B surface antigen positive
10. Auto-immune hepatitis
11. Auto-immune cholestatic disorders
12. Wilson's disease
13. Alpha-1-antitrypsin deficiency
14. Hemochromatosis or secondary iron overload
15. Severe steatohepatitis
16. Drug-induced liver disease
17. Child-Turcotte-Pugh Score ≥ to 7
18. History of bleeding from either esophageal or gastric varices
19. Platelet count < 50,000/ mm^3
20. Neutrophil count < 1,000/mm^3.
21. Hematocrit <33% or hemoglobin <11 gm/dL
22. Alpha-fetoprotein > 200 ng/mL or >1000 ng/mL for Express patients
23. Hepatic mass lesion suspicious for hepatocellular carcinoma
24. Renal insufficiency
25. A positive test for HIV
26. Diabetes not under control
27. Hemophilia
28. Organ, limb or bone marrow transplant
29. Use of chronic medications such as immunosuppressive meds (corticosteroids, methotrexate, azathioprine) or coumadin
30. Active systemic auto-immune disorders
31. Malignancy diagnosed and/or treated within the past 5 years (other than localized squamous or basal cell cancer)
32. Serious cardiac, cerebrovascular or pulmonary disease
33. Underlying hematologic abnormalities that would preclude treatment with interferon
34. Seizure disorder not well controlled by medication within past 2 years
35. Patient is pregnant or breast feeding
36. Male partner of a woman who is pregnant or breastfeeding
37. Active alcohol abuse within the past 12 months
38. Illicit drug use within the past 2 years
39. Does not meet psychiatric disorder criteria per protocol
40. Intolerance to previous interferon therapy
41. Unable to provide informed consent
42. Signed informed consent, but no longer willing to participate
43. Unwilling to undergo three liver biopsies over 4 years
44. Serum bilirubin > 2.5 mg/dL that is not due to Gilbert's syndrome or ribavirin
45. Participating in another clinical trial
46. Prior non-response to interferon treatment not appropriately documented
47. Unwilling to participate due to possible side effects of medication
48. Unwilling to participate due to possibility of being randomized to control (untreated) group
49. Unwilling to participate due to long duration of Trial
50. Unwilling to participate in an experimental research study
99. Other (Specify above in B1 – B4)