

HALT-C Trial

Randomization Checklist II (Express & Breakthrough/Relapse)

Form # 99 Version A: 06/15/2000

SECTION A: GENERAL INFORMATION

- A1. Affix ID Label Here -> []
A2. Patient initials:
A3. Visit number:
A4. Date Completed: MM / DD / YYYY
A5. Initials of person completing form:

SECTION B: RANDOMIZATION CHECKLIST - To be completed for Express patients and Breakthrough/Relapse Patients to be randomized in the HALT-C Trial.

- B1. Ishak fibrosis score (from central review of entry biopsy)
2 - 4 1
5 - 6 2
Breakthrough/Relapse: use Screening bx
Express patients: use pre-treatment bx

- B2. Child-Turcotte-Pugh score:
a. First Score: []
b. 2nd Score: []
(Note: At least one score must be less than 7 for randomization)

- B3. Central HCV RNA test result(s):
Positive 1
Negative 2
Must be positive for randomization:
Breakthrough/Relapse at 2 separate time points
Express patients during Screening

- B4. Alpha-fetoprotein result:
_____ ng/mL
(Note: Must be less than or equal to 1000 ng/mL for randomization)

- B5. Is there evidence of hepatocellular carcinoma?
Yes 1
No 2
(Note: Ultrasound must have been completed and reviewed.)

- B6. All required laboratory tests or procedures have been done, and results evaluated.
Yes 1
No 2

- B7. Is this patient eligible for randomization?
Yes 1
No 2 (END OF FORM)

- B8. Is this patient willing and appropriate for randomization?
Yes 1
No 2 (END OF FORM)

- B9. Are you sure you want to randomize this patient?
Yes 1 (Extra verification for use during data entry.)