

HALT-C Extended Follow-up Visits

Patients who complete Month 48 will be offered an “extended follow-up” visit after their Month 54 study visit at Month 60 and Month 72 through April 2007. These visits will primarily be to identify outcome events, and to provide information to patients concerning the current status of the trial. Some questionnaires, blood tests, and an ultrasonogram will be performed. This visit is not to take the place of patients establishing a relationship with a primary care or liver specialist physician once the Month 54 visit is completed.

Extended Follow-up Visit Eligibility

Eligibility for the Extended Follow-up Visits Month 60 and Month 72 was based upon the following rules:

- The Month 60 and Month 72 Visit windows must open by April 1, 2007 in order for the visit to be expected.
- End of the Study Visit for Month 60 or Month 72 is on or before April 30, 2007 when the last patient visit will occur for the HALT-C Trial.
- The patient must give consent to the Extended Follow-up Visits, as indicated on Form #604: Extended Follow-up Trial Consent.

All sites were notified of potential candidates for the Extended Follow-up Visits and consented these patients according to their IRB approved consent form. Form #604 is data entered into the Data Management System in the Study Visit Month 48 and triggers the addition of the Month 60 only or Month 60 and Month 72 Visits to the DMS.

No data on Adverse Events or Serious Adverse Events will be collected at these two visits. The following tests, interviews, and forms are done during the Extended Follow-up Phase:

Interviews

- Form #610: Study Visit. This Form is modified to collect data on any possible outcome and antiviral medications the patient may have used since Month 54.

Tests

- Form #611: Physical exam
- Form #622: Ultrasound, MRI, CT evaluation of the liver

Local lab tests (Form #630)

- Fasting serum chemistries (creatinine only)
- Liver chemistries (AST, ALT, alkaline phosphatase, total bilirubin, albumin, and globulin [or total protein])
- Complete blood count with differential (WBC, neutrophils, hematocrit, hemoglobin, platelets)
- Prothrombin time (INR)
- Alfa-fetoprotein (AFP)

Central lab tests (Form #673)

- 4 serum aliquots (sent to central repository for future study as yet to be determined).

Forms

- Form #604: Extended Follow-up Trial Consent (data enter in the Month 48 visit)
- Form #610: Extended Follow-up Study Visit

- Form #611: Extended Follow-up Physical Exam
- Form #615: Extended Follow-up CTP Score
- Form #622: Extended Follow-up Ultrasound (MRI, CT)
- Form #630: Extended Follow-up Local Lab
- Form #673: Extended Follow-up Visit Aliquot Form
- Form #63: Clinical Outcome (if applicable)
- Form #64: Death Report (if applicable)
- Form #66: HCC Diagnosis (if applicable)
- Form #67: Liver Transplant Date (if applicable)