

NCCTG Eligibility Checklist N04C2

7/13/2007
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Study reg. number _____

Eligibility Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.
Yes No

Inclusion Criteria

- ____ ____ ≥18 years of age. Age = _____
- ____ ____ Current or previous histologic or cytologic proof of malignancy (except lymphoma).
- ____ ____ Treating oncologist thinks that ascites is caused by cancer (positive cytology is not necessary).
- ____ ____ Therapeutic paracentesis planned ≤3 days after randomization or completed in the preceding 2 days prior to randomization.
- ____ ____ Patient views ascites as a problem (documentation not necessary).
- ____ ____ Must be willing to give ascites fluid sample for research.
- ____ ____ Ovarian cancer patients at Mayo Rochester must be willing to give a blood sample for research.

All responses in above section must be “Yes.”

Exclusion Criteria

- ____ ____ History of cholecystitis with no cholecystectomy.
- ____ ____ Known allergy to subcutaneous octreotide (Sandostatin®) or depot octreotide (Sandostatin LAR® Depot).
- ____ ____ Known latex allergy.
- ____ ____ Patients with known history of chronic renal failure (defined by serum creatinine ≥2 x UNL). It is not necessary to obtain a serum creatinine in patients who do not have a history of renal disease.
- ____ ____ Any medical condition that may interfere with ability to receive protocol treatment.
- ____ ____ Life expectancy <4 weeks.
- ____ ____ Lymphomatous ascites.
- ____ ____ Any of the following:
 - Pregnant women
 - Nursing women
 - Men or women of childbearing potential who are unwilling to employ adequate contraception
- ____ ____ Currently receiving octreotide or depot octreotide (Sandostatin LAR® Depot).
- ____ ____ Patient is receiving intraperitoneal chemotherapy.
- ____ ____ On coumadin or warfarin or at high risk for bleeding from a procedure. (Prophylactic warfarin 1 mg/day is permitted.)
- ____ ____ Currently or about to receive first-line chemotherapy for any cancer other than pancreatic cancer. (Second-line chemotherapy or later-line chemotherapy is allowed.)
- ____ ____ Currently receiving bevacizumab.
- ____ ____ Known cirrhosis or portal hypertension.
- ____ ____ Uncontrolled diabetes mellitus.

All responses in above section must be “No.”

____ ____ Patient eligible.

Registration Check - Answer questions below (yes/no). All requirements must be confirmed. All dates are to be M/D/Y.
Yes No

- ____ ____ Consent form signed and dated. Date of consent ____-____-____.
- ____ ____ **Is this an USA institution?** (This question may be answered yes or no.)
 - ____ Yes → Complete authorization question below.
 - ____ No → Check “not applicable (**Non-USA institution only**)” and go to next question.
- ____ ____ Authorization for use and disclosure of protected health information signed and dated.
- ____ ____ Date of authorization ____-____-____ vs. not applicable (**Non-USA institution only**) ____.
- ____ ____ Treatment on this protocol must commence at the accruing membership under the supervision of a NCCTG member physician.

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Registration Check – (continued)

Yes No

- Treatment cannot begin prior to registration and must begin ≤ 48 hours after paracentesis.
- Pretreatment tests/procedures must be completed within the guidelines specified on the test schedule (see Section 4.0).
- All required baseline symptoms must be documented and graded.
- Study drug availability checked.

- Randomization Center will register patients separately to the translational research component of this study (see Section 14.0)
- Patient has given permission to give ascites sample for research testing.

Is this a Mayo Rochester patient with ovarian cancer?

- Yes \rightarrow Complete next question
- No \rightarrow Skip the next question
- Patient has given permission to give blood sample for research testing (**required for Mayo Rochester patients with ovarian cancer.**)

All responses in above section must be “Yes.”

- Randomization/registration allowed.

Stratification Factors

- Ongoing chemotherapy anticipated
- Yes
- No

- Frequency of paracentesis prior to enrollment
- Never
- Other

- At registration, patient has received chemotherapy
- Never
- Only first-line chemotherapy
- Second-line chemotherapy
- Other

Descriptive Factors

- Cancer type
- Ovarian cancer
- Primary peritoneal cancer
- Gastrointestinal cancer
- Other

- Ongoing diuretic therapy anticipated
- Yes
- No

- Liver metastases in $>25\%$ of the liver
- Yes
- No

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Assigned Treatment

Contact person (data manager/nurse/pharmacist) name: _____
Contact person may not be involved in assessing adverse events or any other outcome measure.
(See Section 6.31.)

Contact person (data manager/nurse/pharmacist) phone number: _____

_____ Depot Octreotide (Sandostatin LAR Depot) vs. Placebo

Treatment assignment number: _____

Person registering _____ Random. specialist _____
Signature Signature initials

Physician _____ M D Y _____
Signature