NSABP B-39/RTOG 0413 A Randomized Phase III Study of Conventional Whole Breast Irradiation (WBI) Versus Partial Breast Irradiation (PBI) for Women with Stage 0, I, or II Breast Cancer

Fast Facts for NSABP B-39/RTOG 0413

- NSABP B-39/RTOG 0413 is the key to answering the question, “Is partial breast irradiation (PBI) safe and as effective as whole breast irradiation (WBI) for these patients?” Mature Phase III data documenting the long-term efficacy of PBI and the group of patients most suitable for its application are not yet available. Since the majority of patients treated in the Phase III PBI studies were highly selected and treated at a handful of institutions, it remains to be determined if the excellent results observed to date are a reflection of the true efficacy of PBI or to other confounding factors. The only scientifically valid approach to resolve this concern is in the completion of a well-designed, sufficiently powered Phase III study comparing outcome in similarly staged and selected patients randomized between standard WBI versus PBI which is NSABP B-39/RTOG 0413.

- A bilateral breast MRI cannot be substituted for the required bilateral mammogram.
- All patients, including WBI patients, are to be treated at a credentialed facility.
- If the patient cannot receive the selected PBI technique and the plan is to administer WBI, the case should not be submitted for WBI review.
- Remember to submit your QOL forms for patients who are enrolled in the BAHO sub-study for B-39/0413. A secondary endpoint of the trial is to determine if PBI produces less fatigue and treatment-related symptoms compared to WBI.
- Remember to submit your cosmesis evaluations and digital photos. One of the secondary aims of the trial is to determine whether PBI delivered on 5 treatment days over a period of 5 to 10 days can provide a comparable cosmetic result to WBI.
- Remind the radiation oncologists and surgeons at your site that the NSABP B-39/RTOG 0413 trial is still accruing and with their help accrual to this trial can be completed.

NSABP B-39/RTOG 0413 Accrual

As of July 24, 2012 there were 4,152 patients entered on the trial. Only 148 patients are needed to complete accrual.

Top 5 NSABP Accruing Centers
1. Virginia Commonwealth University
2. Tied for #2 are: William Beaumont Hospital CCOP and Center Hospitalier Affilie Universitaire de Quebec, Hopital du St-Sacrament
3. Kalamazoo, Michigan CCOP
4. University of Miami

Top 5 RTOG Accruing Centers
1. Arizona Oncology Services Foundation
2. Huntsman Cancer Institute at University of Utah
3. Tied for #3 are: London Regional Cancer Center, Ontario and University of Colorado
4. Cross Cancer Institute

Congratulations to all of the Top Accruing Centers – All of your hard work in accruing patients to this very important trial is appreciated by NSABP and RTOG! Keep screening potential patients. Will your site be in the top 5 with the next B-39/0413 update??

NSABP B-39/RTOG 0413 Protocol Team
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Thomas Julian, MD (NSABP) / David Parda, MD (NSABP) Protocol Officers
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Rachel Rabinovitch, MD (RTOG) Protocol Co-Chairs
Joseph Costantino, DrPH (NSABP) / Kathryn Winter, MS (RTOG) Protocol Statisticians

If you have any questions or topics to be addressed in future e-mail updates (such as common obstacles in accruing to this trial), please contact the Clinical Coordinating Division (CCD) at (800) 477-7227 or ccd@nsabp.org.

If you have any questions concerning eligibility and clinical aspects of the trial, contact the Clinical Coordinating Division at (800) 477-7227 or ccd@nsabp.org.