POSITIVE (IBCSG 48-14/BIG 8-13/A221405): A Study Evaluating Pregnancy and Disease Outcome and Safety of Interrupting Endocrine Therapy for Young Women with Endocrine Responsive Breast Cancer Who Desire Pregnancy

O Pagani, A Partridge, HA Azim Jr, F Peccatori, M Ruggeri, R Gelber, Z Sun

International Breast Cancer Study Group

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Background

- Young breast cancer (BC) patients often face the disease before completing their family planning. The best available retrospective evidence suggests that pregnancy after early stage BC does not negatively impact disease outcome in patients with endocrine sensitive BC and is safe for the offspring.
- Given the indication for prolonged endocrine therapy (ET) (5-10 years) for some women it is not feasible to wait until completion of therapy and thus there is a need to explore the safety of temporary interruption of ET to allow pregnancy.
- To date, no definitive prospective study has been conducted in young women desiring pregnancy after BC.

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Objective

To assess the risk of BC relapse associated with temporary interruption of endocrine therapy (ET) to permit pregnancy, and to evaluate pregnancy success rate and offspring outcome.

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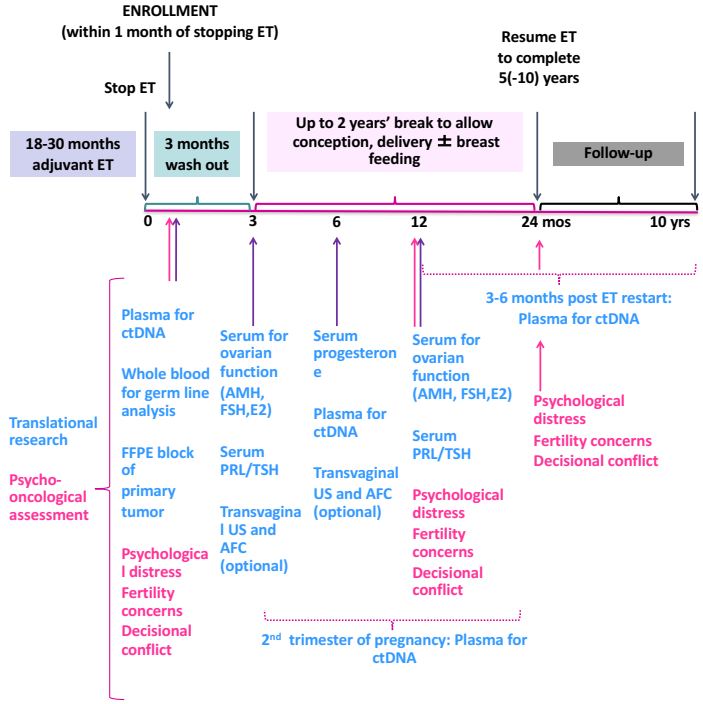
Study Design



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Methods

- Prospective observational study of endocrine therapy (ET) interruption to attempt pregnancy among women with early stage hormone-sensitive breast cancer; no planned active drug intervention.
- Evaluates BC outcome, patient adherence to protocol, pregnancy and offspring outcome.
- Primary efficacy endpoint of breast cancer-free interval (BCFI) defined as the time from enrollment in the study to the first invasive BC event.
- Assuming true risk of BC recurrence for patients who do not interrupt ET is 2% per year, with 500 patients enrolled in 4.0 years and an additional 1.6 years of follow-up, there will be a median follow-up of approximately 3 years at the time of the primary analysis, anticipated to occur 5.6 years after enrollment of the first patient. We anticipate 31 BC recurrences and an estimated 3-year BCFI failure of 5.6% (95% CI 4.0% to 7.9%).
- Patients will be followed for 10 years after enrollment. Total duration including long-term follow-up will be 14 years.

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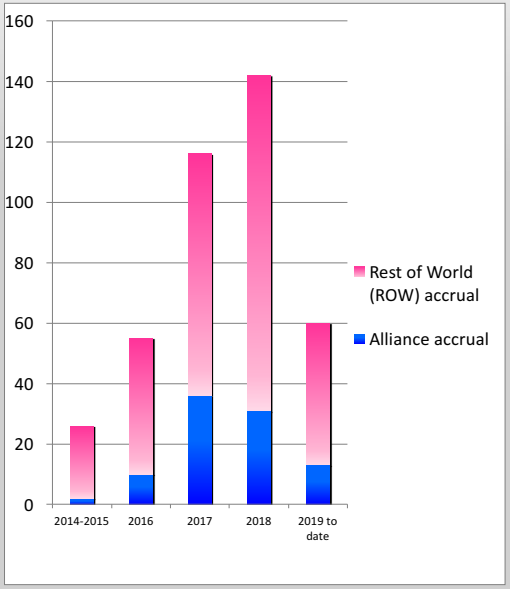
Accrual



- Current accrual: 399 patients (Apr 30, 2019)
- Target accrual: 500 (11 patients/month)
- Expected accrual completion: Middle of 2020

- **Open to enrollment worldwide**

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Patient Population

- Histologically-proven stage I-III endocrine-responsive BC.
- Wishes to become pregnant.
- Age ≥ 18 and ≤ 42 years at enrollment.
- Premenopausal status at BC diagnosis.
- Adjuvant endocrine therapy (SERM alone, GnRH analogue plus SERM or AI) for ≥18 months but ≤30 months, stopped within 1 month prior to enrollment.

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Related Research

- Translational research: fertility, pregnancy and BC biology determinants (e.g. ovarian function, uterine evaluation and circulating tumor DNA).
  FFPE tissue of the primary tumor will be collected to investigate several parameters related to biology of BC in young women.

- Psycho-oncological companion study: prospective evaluation of psychological well-being, fertility concerns, and decisional conflict. Mandatory in the United States and open to interested centers elsewhere.

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