



Pre-mastectomy radiotherapy feasibility trial to facilitate immediate autologous breast reconstruction: A prospective cohort within a randomized clinical trial

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Background

- Women requiring postmastectomy radiotherapy (PMRT) often must delay immediate reconstruction
- Patients undergoing immediate reconstruction and PMRT may have increased complications and poor cosmetic outcomes¹
 - Resulting psychological distress
 - Multiple procedures
- Neoadjuvant radiotherapy (NRT) is utilized in other cancer types with improved oncologic outcomes
- More recently, a few prospective studies of NRT in breast cancer have been done²⁻⁷
- This is the first trial of NRT to facilitate immediate breast reconstruction in patients with breast cancer in the US
- We hypothesize that NRT will:
 - Result in increased number of patients completing immediate autologous breast reconstruction following mastectomy
 - Be technically feasible
 - Have minimal complications

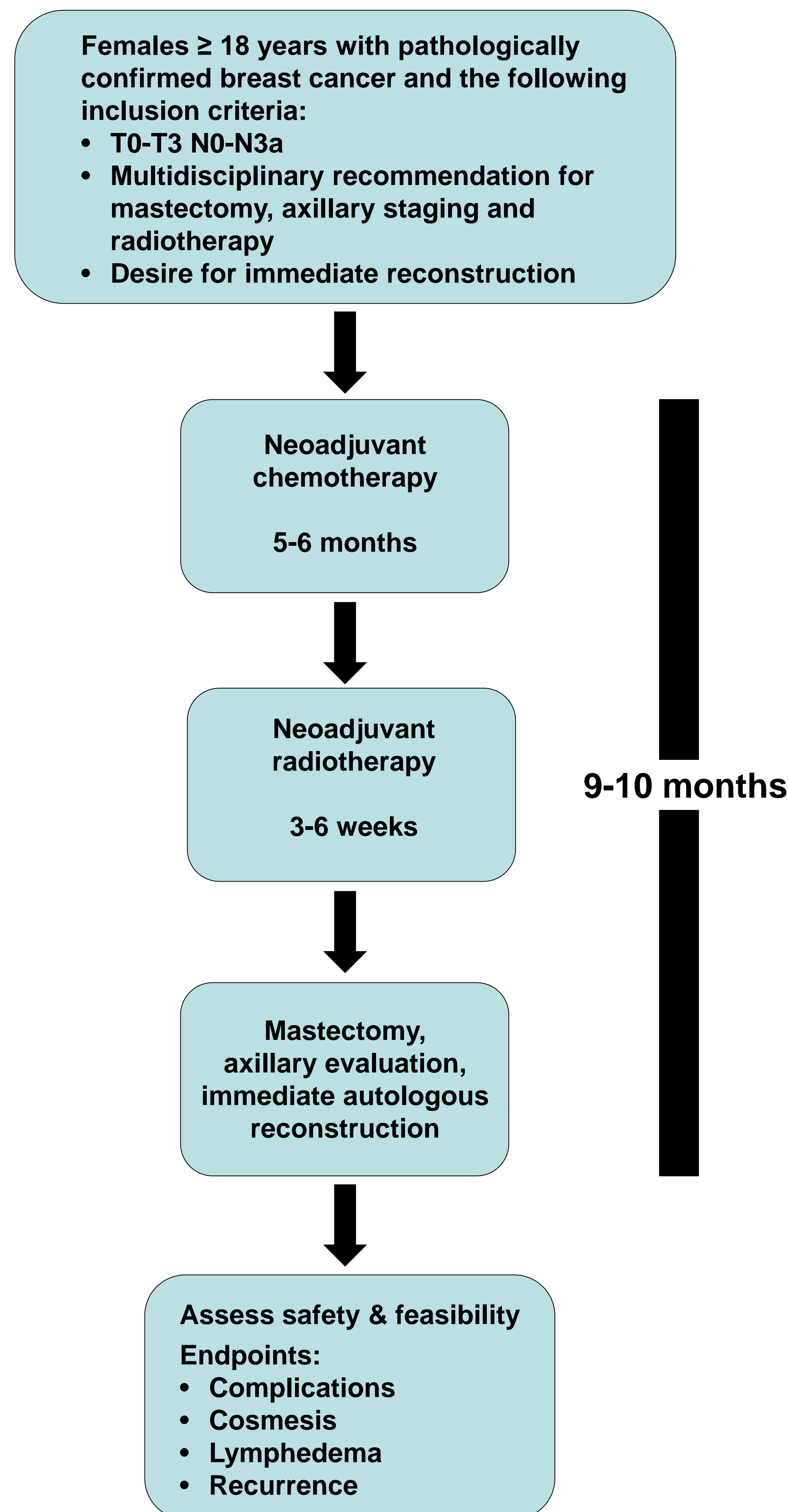
Clinical Trial Design

- Prospective cohort of patients undergoing NRT is embedded in a randomized controlled trial of hypofractionated (3 weeks) versus conventionally fractionated regional nodal irradiation (5 weeks)
- NCT02912312, PI: Karen Hoffman

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Figure 1.
Clinical trial schema



Study Endpoints

- Delays to surgery due to radiation skin and soft tissue effects
- Technical intraoperative complications
- Ability to perform targeted axillary dissection and sentinel node biopsy
- Abortion of reconstructive procedure due to radiation skin, soft tissue or recipient vasculature effects with need to place implant/TE
- Evaluation of surgical and reconstructive complications relating to the time between surgery and radiation and fractionation type
- Mastectomy skin flap necrosis requiring reoperation or debridement
- Complete or partial autologous flap loss
- Surgical recipient site delayed wound healing and infectious complications
- Primary aim of the encompassing RCT: risk of lymphedema, defined as 10% increase in volume using perometer measurements between the affected and unaffected arms over 24 months
- Oncologic outcomes: locoregional recurrence, distant metastases, disease-free survival and overall survival

Statistical Methods

- Descriptive statistics to assess endpoints
- Univariate and multivariate analyses will be done to determine any associations with outcomes

Present and Planned Accrual

- 30 patients will be enrolled – 4 currently enrolled
- If after first 15 patients there are 5 reconstruction failures, the cohort will cease accrual
- 290 patients is accrual goal for RCT – 154 enrolled

References

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