DEVELOPING CONCEPT

A Phase 3 Randomized Placebo Controlled Clinical Trial of Donepezil in Breast Cancer Survivors with Symptoms of Cognitive Dysfunction following Chemotherapy

PI: Julia Lawrence, DO
Associate Professor
Hematology & Oncology
Wake Forest University School of Medicine
jalawren@wakehealth.edu

Chemo-Associated Cognitive Dysfunction

- ‘Chemobrain,’ ‘chemofog’ common
- 16-75% suffer some cognitive impairment
- Impairment can be chronic
- Significant impact on QOL
- Donepezil efficacious with cancer pts (91105)
- 97211 demonstrated feasibility with this population
  - 10 subjects/month
  - Retention at 24 weeks was 72%
  - Of those who completed study adherence to drug and all assessments was 95%

Study Design

Women selected for subjective symptoms of cognitive impairment (FACT-Cog)

Stratification factors

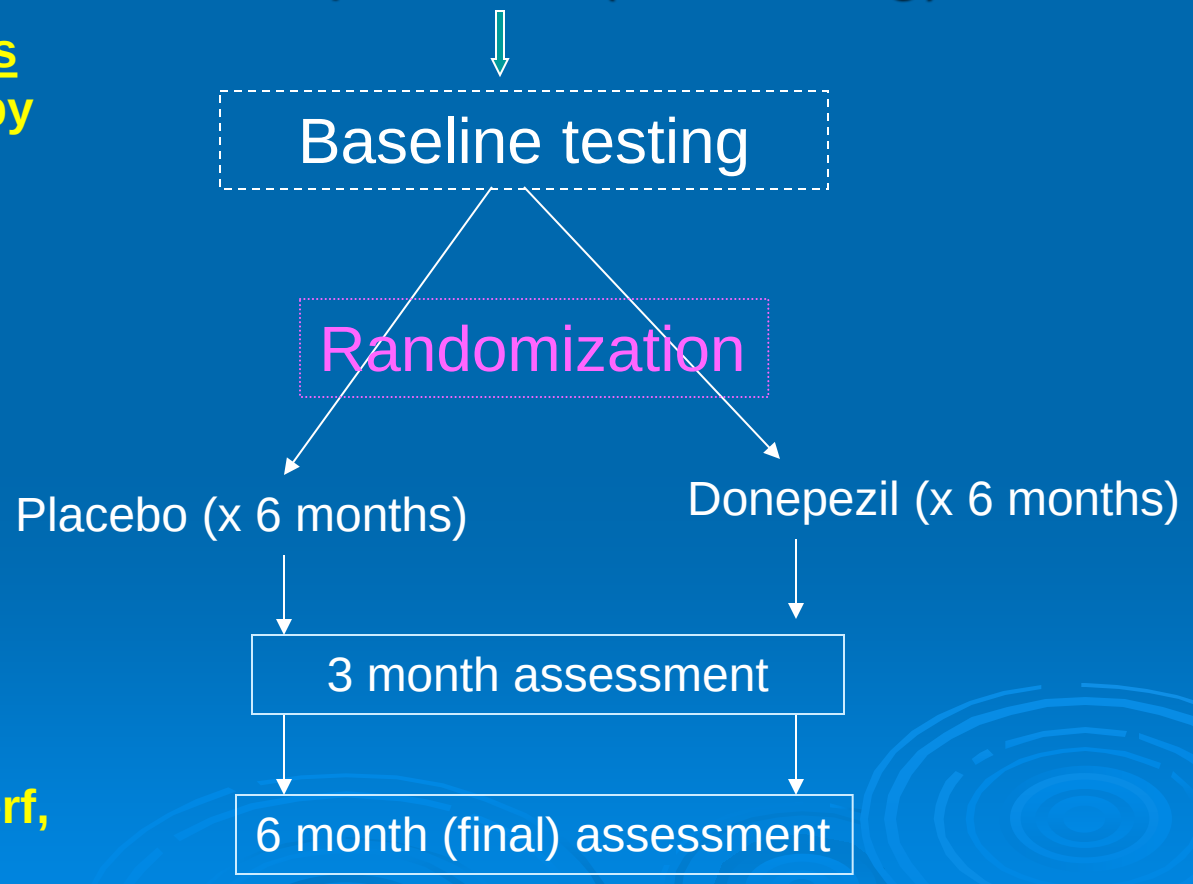
1) **Hormonal therapy**
2) **Age > 60 yrs**

Donepezil Dose

5 mg/d x 6 wk +
10 mg/d x 18 wk

Outcomes

1^0 :Verbal memory
2^0 : Cog sxs, cog perf, QOL



Eligibility Criteria

- Women with invasive breast cancer who received adjuvant chemotherapy between 1-5 years previously
- Subjective report of cognitive sxs related to cancer/treatment
- ≥ 4 cycles of adjuvant chemotherapy
- No clinical evidence of recurrent disease
- No history of dementia or CVA
- Use of psychotropic meds is permitted if dose has been stable for prior 6 months

Pre-Eligibility Screen

- FACT- Cognition (Version 3) Perceived Cognitive Impairment (PI) subscale
- An entry level score of < 63 is required.

Study Status

- Concept being finalized
- Expected submission to NCI – 11/2013
- Projected N = 178
- Projected duration = 3 yr.