A randomized double-blind placebo controlled, Phase II/III, study of aromatase inhibitors and transdermal testosterone in the adjuvant treatment of postmenopausal women with aromatase inhibitor induced arthralgias: A221102

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Testosterone undecanoate treatment reduces joint morbidities induced by anastrazole therapy in postmenopausal women with breast cancer: results of a double-blind, randomized phase II trial

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Australia
Trial Design

90 women on adjuvant anastrazole 1mg per day plus

3 months of placebo or testosterone undecanoate (TU)

30 = placebo

30 = 40mg TU

30 = 80mg TU
Percentage of patients with a PAIN VAS >50mm

Placebo 40 mg TU 80 mg TU

Baseline 1 month 3 months

P=0.04
Percentage of patients with a Stiffness VAS >50mm

- Placebo
- 40 mg TU
- 80 mg TU

Baseline, 1 month, 3 months

P=0.06
Estradiol concentrations

- Baseline
- 1 month
- 3 months

Placebo 40 mg TU 80 mg TU
Free Testosterone Concentrations

![Bar chart showing Free Testosterone Concentrations at different time points (Baseline, 1 month, 3 months) for Placebo, 40 mg TU, and 80 mg TU.]
Randomized Placebo-Controlled Trial of Testosterone for AI-related Joint Symptoms

Eligibility:
• Postmenopausal
• Adjuvant AI
• Worst joint pain score ≥ 5/10

Primary Outcome: Change in joint pain score at 3 mos

N=226
Other Eligibility Factors

- Receiving anastrozole or letrozole
- Body Mass Index (BMI) between 18 and 35 kg/m2
- Must have BOTH ER and PR receptor-positive tumors and BOTH must be ≥ 26% positive. Alternatively, if ER and PR are determined by Allred score, the score needs to be 5 or higher
Recent Protocol Modification

• Change from SubQ preparation to a topical daily preparation