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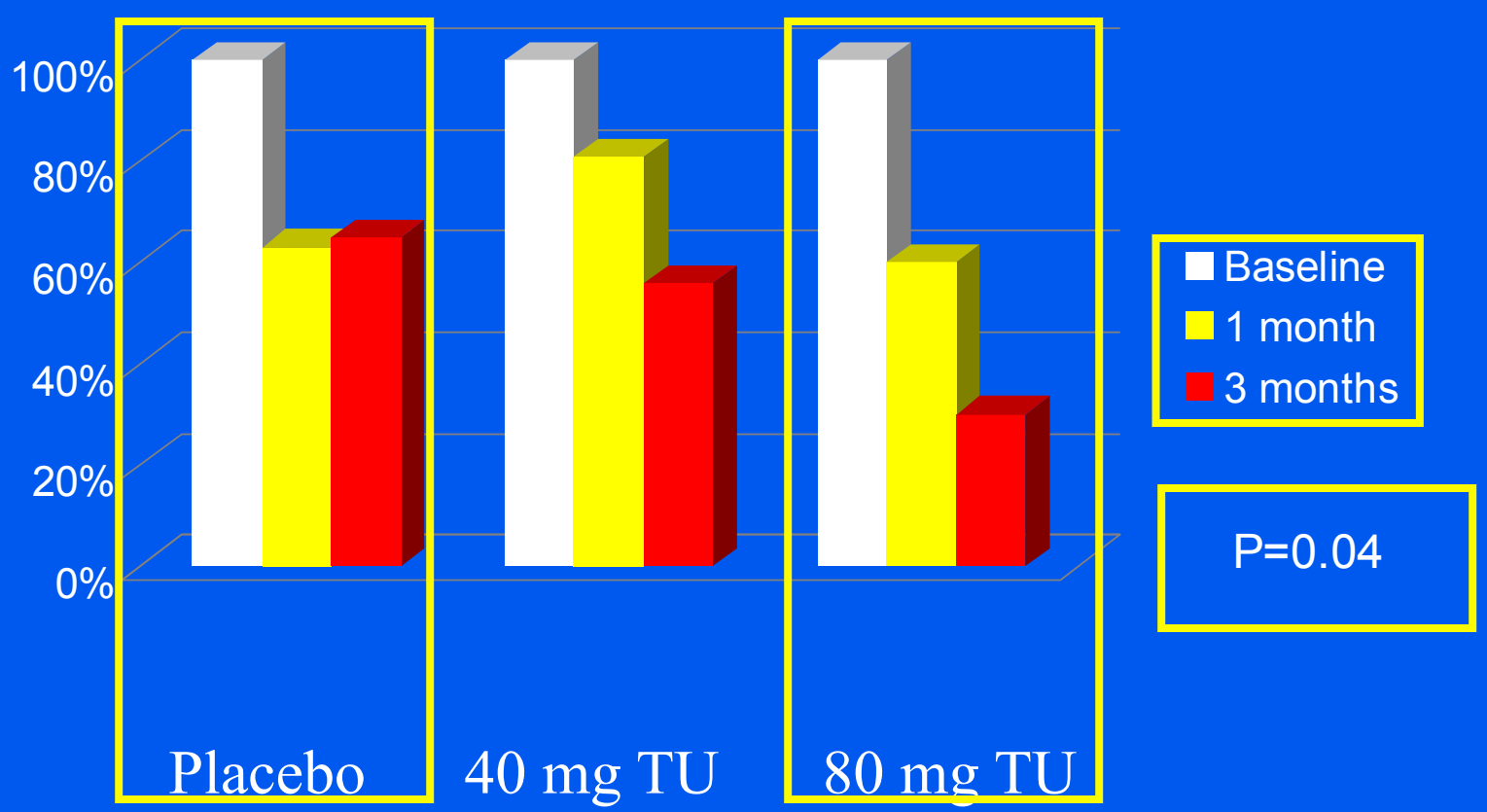
Testosterone undecanoate treatment reduces joint morbidities induced by anastrazole therapy in postmenopausal women with breast cancer: results of a double-blind, randomized phase II trial

Birrell SN and Tilley WD.

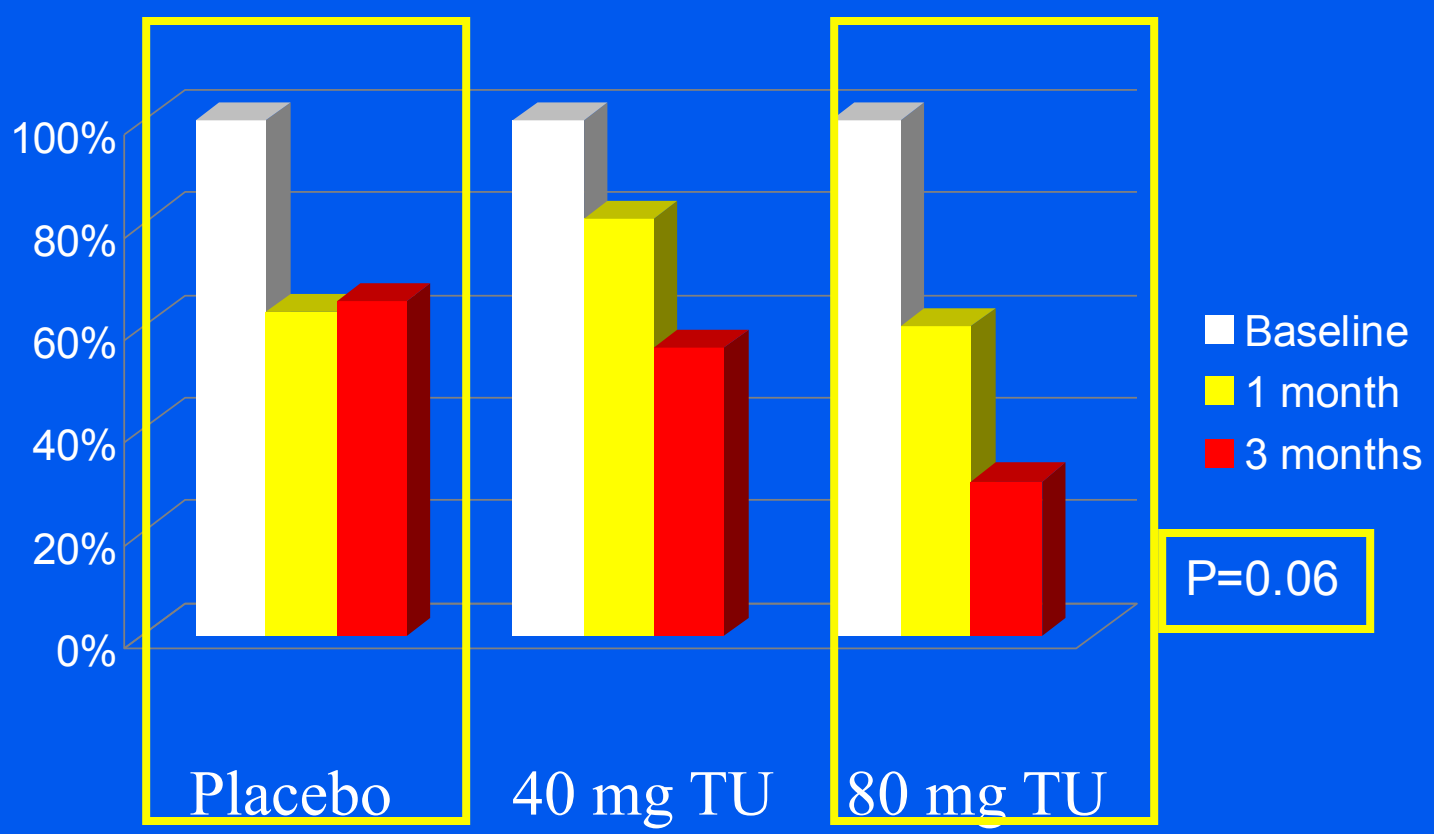
Australia

Trial Design

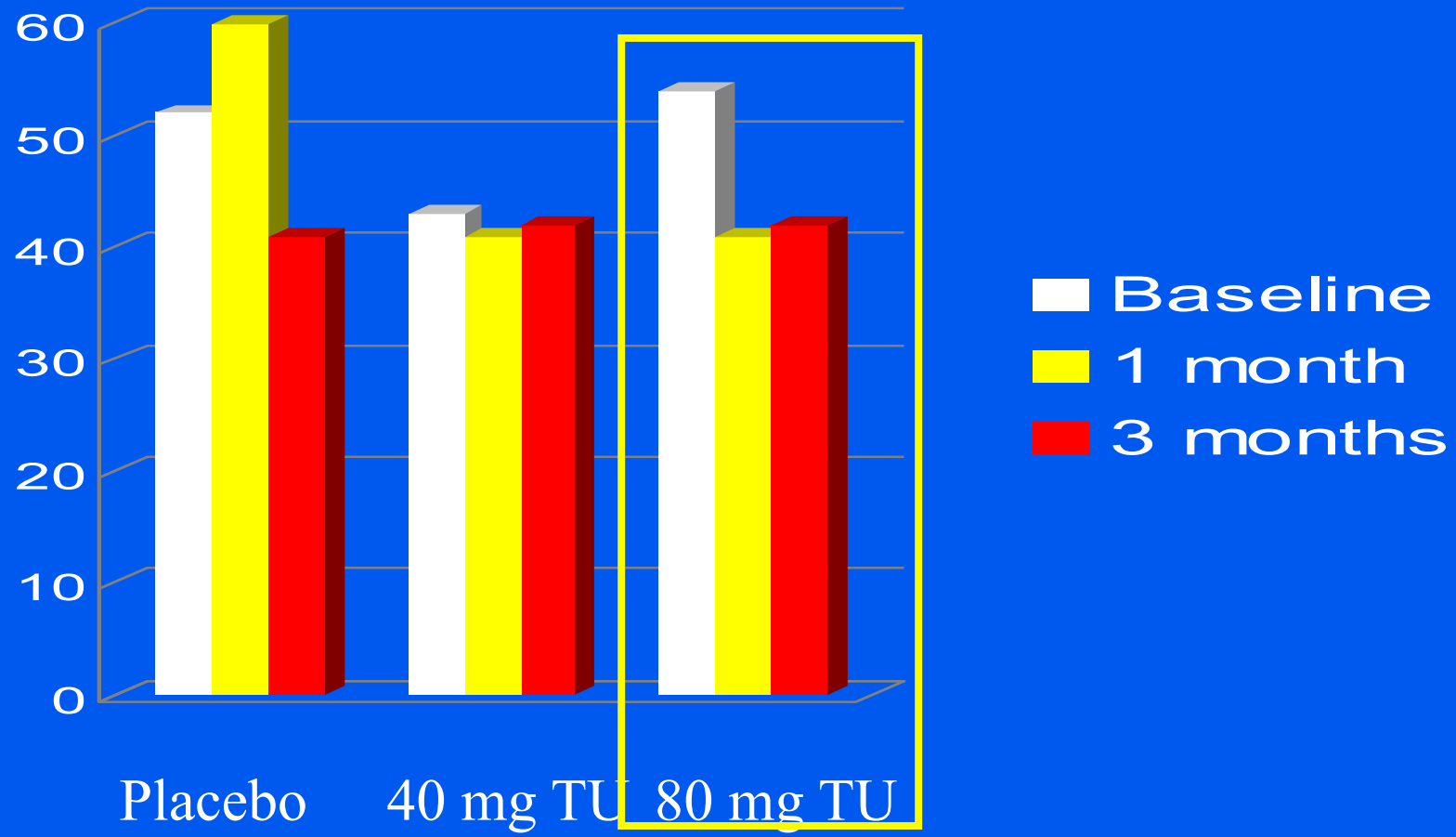
Percentage of patients with a PAIN VAS >50mm



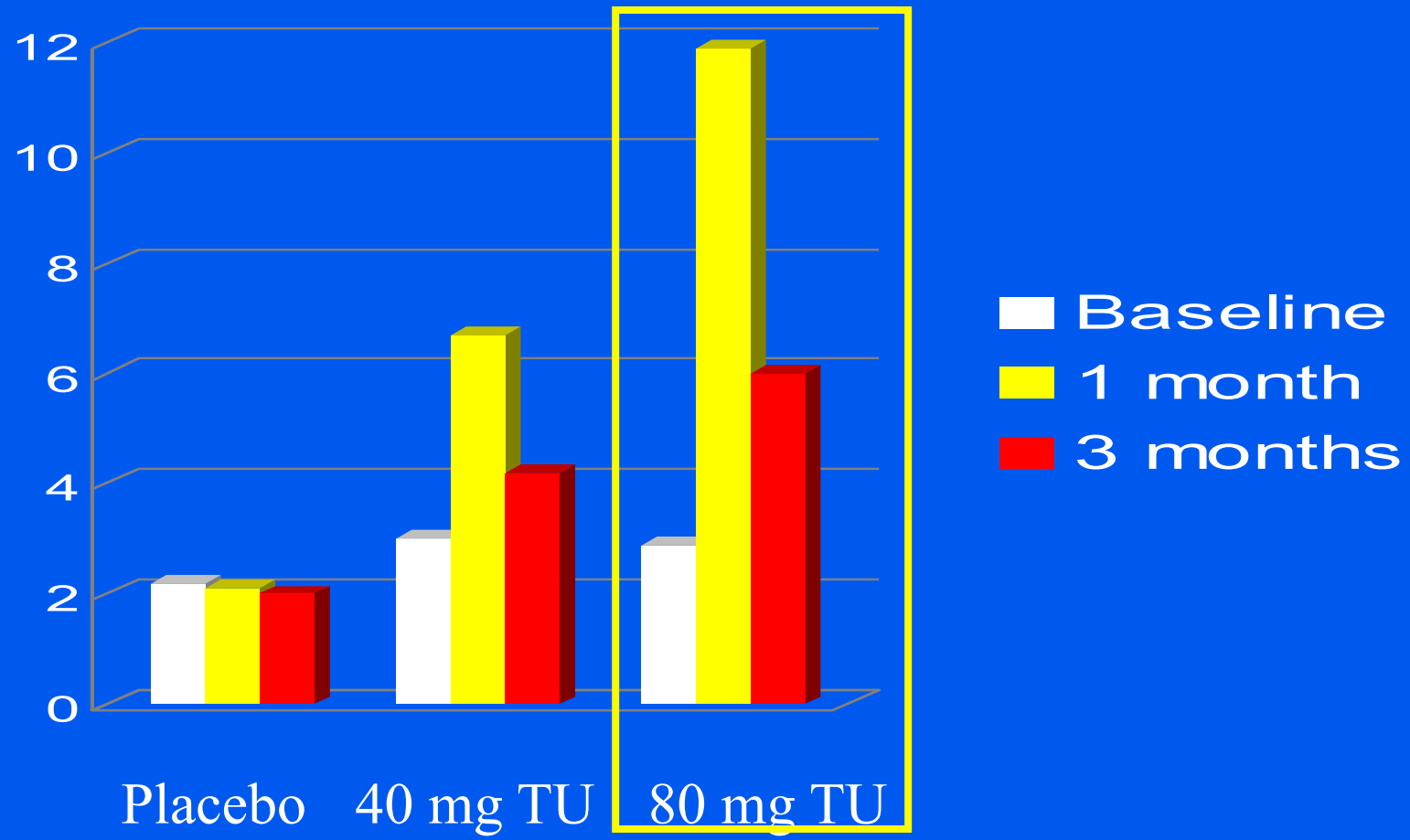
Percentage of patients with a Stiffness VAS >50mm



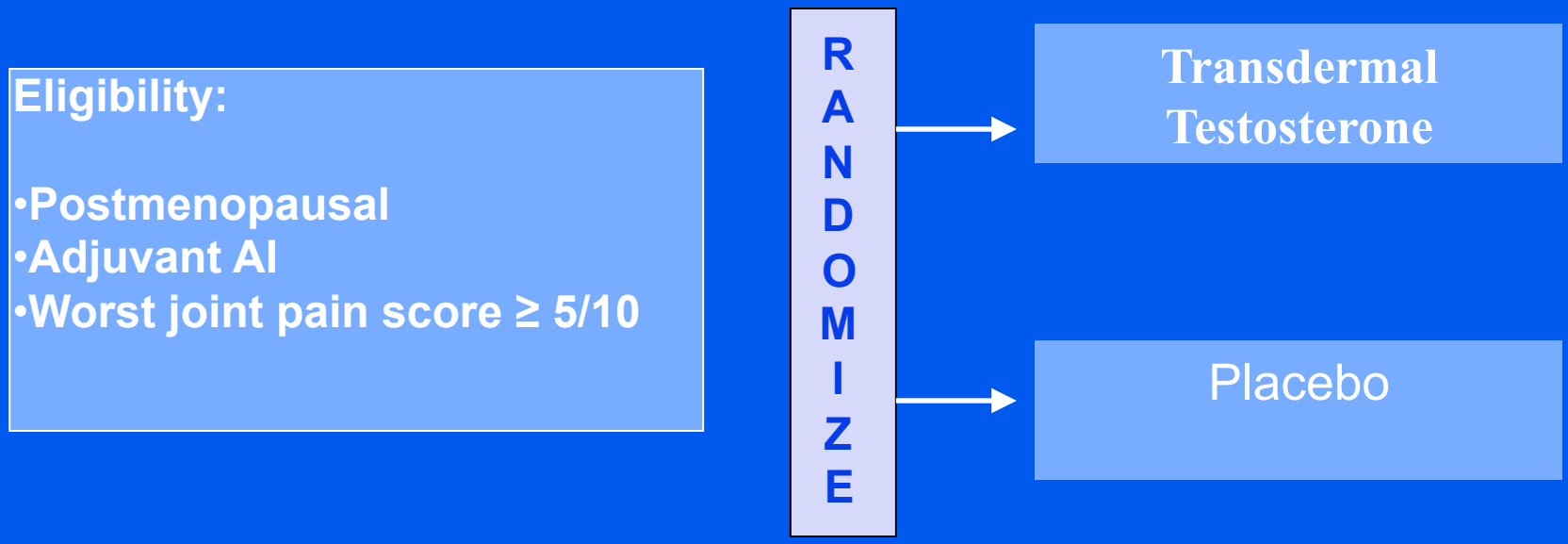
Estradiol concentrations



Free Testosterone Concentrations



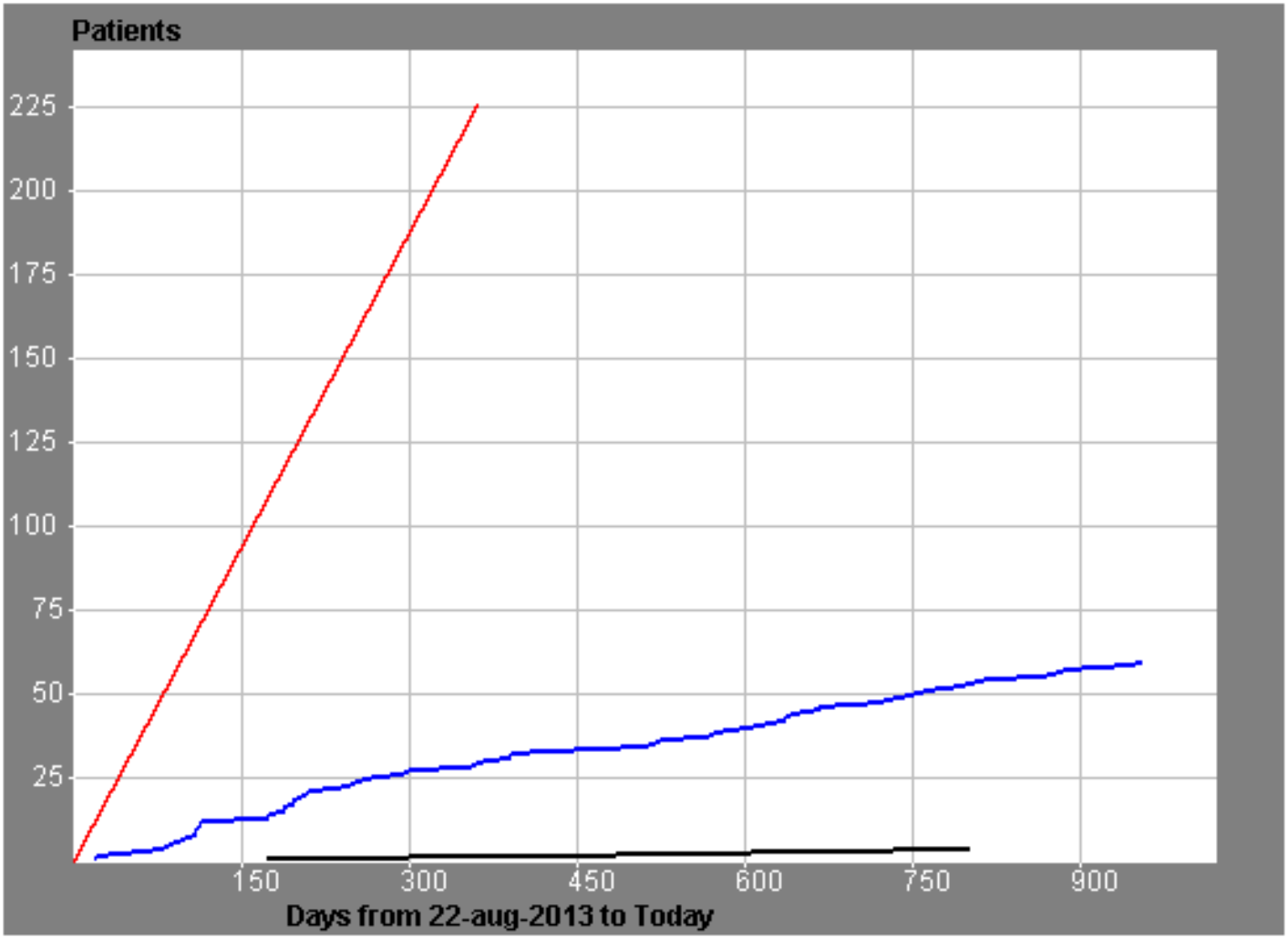
Randomized Placebo-Controlled Trial of Testosterone for AI-related Joint Symptoms



Primary Outcome: Change in joint pain score at 3 mos

N=226

Study = A221102



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
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Recent Protocol Modification

- Change from SubQ preparation to a topical daily preparation