Dr. Dawn Hershman

Third generation aromatase inhibitors have been shown to be superior to tamoxifen in improving disease free survival, decreasing distant and local recurrence rates and decreasing incidence of contra-lateral breast cancer in women with early stage hormone receptor positive breast cancer. However, up to 50% of women on AI report symptoms of debilitating musculoskeletal pain and joint arthralgia that can lead to noncompliance and early discontinuation, thereby impacting survival. Our previous phase II randomized study (n=40) showed that acupuncture administered twice weekly for 6 weeks compare to sham acupuncture improve AI induced joint pain/stiffness as measured by modified Brief Pain Index short form (mBPI-sf) worse pain score by 50%. The proposed phase III randomized, sham controlled, blinded, multi-centered clinical trial will look at the effects of acupuncture on joint pain/stiffness that started or increased since initiation of AI in 200 women with Stage I-III breast cancer. Women will be recruited from four institutions and randomized to either true acupuncture or sham acupuncture administered twice weekly for 6 weeks follow by maintenance weekly acupuncture or sham acupuncture for 6 weeks. True acupuncture sessions will consists of standardized full body and joint specific point prescription and the NADA auricular protocol. The sham acupuncture treatment will consist of superficial needling at full body and joint specific point prescriptions that do not correspond to any true acupuncture points. The primary hypothesis is that acupuncture administered twice weekly for 6 weeks then weekly for 6 weeks will reduce joint pain/stiffness in women with AI induced arthragia as measured by mBPI-SF scores at 6 weeks compared to sham acupuncture. Secondary endpoints will assess whether weekly maintenance true acupuncture from week 6 to week 12 will maintain the effects seen at week 6 as measured by mBPI-SF score at 12 weeks and whether true acupuncture will have a durable effect as measure by mBPI-SF score at 24 weeks, compared to sham acupuncture. Other secondary endpoint (to be evaluated at baseline, 6, 12 and 24 weeks) include 1) additional assessment of joint pain/stiffness and functional status via self administered questionnaires (Western Ontario and McMaster Universities Osteoarthritis (WOMAC), Modified Score for the Assessment and Quantification of Chronic Rheumatoid Affections of the Hands (M-SACRAH) and Outcome Measures in Rheumatology Clinical Trials and Osteoarthritis Research Society International criteria (OMERACT-OARSI), 2) quality of life assessment via the self administered questionnaire Functional Assessment of Cancer Therapy- Breast/Endocrine subscale (FACT-B/ES), 3) analgesic use, 4) functional testing (grip strength and “timed get up and go’ for lower extremity”) and 5) exploratory hormonal and inflammatory biomarkers. This study will be the first large multi-center center intervention trial looking at the effects of acupuncture on AI induced arthragia in women with breast cancer.
