Trial 1999: Steroids (Danazol)

Randomized controlled trial of the management of premenstrual syndrome and premenstrual mastalgia using luteal phase-only Danazol

Link: https://pubmed.ncbi.nlm.nih.gov/9914571/

Year published: 1999

Pubmed classification: Clinical trial.

Objective: To evaluate the efficacy and side effects of danazol 200 mg daily given only in the luteal phase of the menstrual cycle to treat premenstrual syndrome and premenstrual mastalgia.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo group.

Participant information: The subjects of the study were 100 women who had been referred to the premenstrual syndrome clinic at the North Staffordshire Hospital for the management of premenstrual syndrome and premenstrual breast pain.

Treatment length: 3 cycles.

Drug and dosage: Danazol 200 mg daily given only in the luteal phase; or placebo.

Measuring scales: Outcome measures for the study included assessment of improvement in symptoms measured by specific daily visual analogue scales for 4 principal symptoms of premenstrual syndrome and for premenstrual mastalgia; and assessment of side effects and adverse events.

Efficacy outcomes: Significant improvement in symptoms was seen in visual analog scores for mastalgia in months 1 (P =.03), 2 (P =.004), and 3 (P =.01) of the study during active therapy compared with placebo. No improvement was seen for any other symptom or for the global premenstrual syndrome score.

Side-effects assessment: Side effects on danazol and on placebo were equal and minimal.

Conclusion: Luteal phase-only danazol is not effective for the treatment of the general symptoms of premenstrual syndrome but appears highly effective for the relief of premenstrual mastalgia. This approach to therapy is associated with few side effects.

Considerations for future: Studies of cyclic mastalgia using strict diagnostic criteria are required to see whether the freedom from symptomatic side effects is found in longer-term studies and to determine whether such a regimen avoids potentially detrimental effects on the lipid status.

Trial 1995: Steroids (Danazol)

A randomized, placebo-controlled, crossover trial of Danazol for the treatment of premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/7899538/

Year published: 1995

Pubmed classification: Clinical trial.

Objective: To investigate whether Danazol is more effective than placebo for the treatment of premenstrual syndrome (PMS).

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo controlled - crossover study.

Participant information: 31 women meeting rigorous criteria for a diagnosis of severe PMS over two pre-treatment cycles were enrolled; 28 of these subjects completed at least one cycle of treatment with symptom recordings.

Treatment length: 3 cycles active drug or placebo; 3 cycles active drug or placebo.

Drug and dosage: Danazol (200 mg bid).

Measuring scales: Symptom scores on the Premenstrual Tension Self-Rating Scale (PMTS), Beck Depression Inventory (BDI), and a Visual Analogue Scale (VAS) were compared for the premenstrual week in the last cycle of treatment.

Statistical information: A significant period effect confounded the planned within-subject analysis and therefore, the main treatment comparisons were confined to the first period only.

Efficacy outcomes: For the 16 patients on Danazol, scores on the PMTS decreased by an average of 14.0 (10.7) (standard deviation) points from a baseline of 25.4 (5.6) points. For the 12 patients on placebo, PMTS scores decreased by an average of 3.6 (9.5) points from a baseline of 23.5 (5.8) points (14.0 vs. 3.6; $p = .0133$, unpaired t-test). 7 (43.8%) of the subjects on Danazol achieved a clinically relevant reduction of symptoms into the asymptomatic range (PMTS scores < or = 5) as compared to 1 (8.3%) of the subjects on placebo.

Conclusion: Danazol (200 mg bid) provided greater relief from severe PMS during the premenstrual week than placebo.

Trial 1987: Steroids (Danazol)
A clinical trial using Danazol for the treatment of premenstrual tension

Link: https://pubmed.ncbi.nlm.nih.gov/3545282/

Year published: 1987

Pubmed classification: Clinical trial.

Further trial information: Pilot study.

Blind/double blind? Double-blind.

Randomised? Unknown.

Placebo? Placebo group.

Participant information: 40 women with premenstrual tension.

Treatment length: 3 months.

Drug and dosage: 100mg, 200mg, 400mg danazol, or placebo, administered daily.

Efficacy outcomes: 13 patients withdrew by the third month, usually because they complained of no improvement. They had significantly higher pre-trial symptom scores than those who continued.

In patients treated with danazol, symptom scores for breast pain during the second and third months; and for irritability, anxiety and lethargy during the third month were significantly (P less than 0.05) lower than scores in those given placebo. Most symptoms improved on placebo in the first month but by the third month only three remained improved.

In contrast eight symptoms were improved on 200 mg danazol by the third month. By the end of the trial more than 75% of patients who were still taking danazol were essentially free of breast pain, lethargy, anxiety and increased appetite, but results for other common symptoms were no better than with placebo.