Trial 2004: Comparative (Psychological/SSRIs)

A randomized comparison of psychological (cognitive behaviour therapy), medical (Fluoxetine) and combined treatment for women with premenstrual dysphoric disorder

Link: https://pubmed.ncbi.nlm.nih.gov/12436805/

Year published: 2002

Pubmed classification: Clinical trial.

Further trial information: Pragmatic treatment trial.

Objective: To examine the relative effectiveness of CBT, fluoxetine and combined therapy in women with premenstrual dysphoric disorder.

Blind/double blind? Unknown.

Randomised? Yes.

Placebo? No.

Participant information: 108 women, satisfying the DSM-IV criteria for PMDD with 2 months' prospective confirmation, were recruited into the study; 60 of these completed 6 months of treatment.

Treatment length: 6 months (+naturalistic follow-up 1 year post-treatment).

Drug and dosage: Cognitive behavior therapy (CBT) (ten sessions); Fluoxetine (20 mg daily); or combined therapy (CBT plus Fluoxetine).

Measuring scales: The main outcome measures were premenstrual scores on the Calendar of Premenstrual Experiences (COPE), and the percentage of PMDD cases (DSM-IV diagnostic criteria).

Efficacy outcomes: Significant improvement occurred in all three treatment-groups after 6 months' treatment, assessed by the COPE. Fluoxetine was associated with a more rapid improvement. There were no group differences in the percentage of DSM cases of PMDD post treatment, but at follow-up CBT was associated with better maintenance of treatment effects compared with Fluoxetine.

Conclusion: CBT and fluoxetine are equally effective treatments for PMDD, but the treatments have some differential effects that can be considered in treatment decisions. There appears to be no additional benefit of combining the treatments

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Blind/double blind? Unknown

Randomised? Yes.

Placebo? No.

Participant information: 108 women, satisfying the DSM-IV criteria for PMDD with 2 months' prospective confirmation, were recruited into the study; 60 of these completed 6 months of treatment and all measures before and after treatment.

Treatment length: 6 months (+ 1 year post-treatment follow-up).

Drug and dosage: Cognitive behavior therapy (CBT) (ten sessions); fluoxetine (20 mg daily); or combined therapy (CBT plus fluoxetine).

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Conclusion: CBT and fluoxetine are equally effective treatments for PMDD, but the treatments have some differential effects that can be considered in treatment decisions. There appears to be no additional benefit of combining the treatments.

Trial 1998: Comparative (Medications)

A double-blind trial of four medications to treat severe premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/9722128/

Year published: 1998

Pubmed classification: Clinical trial.

Objective: To determine the efficacy of fluoxetine, alprazolam, propanolol and pyridoxine in the treatment of severe premenstrual syndrome (PMS).

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? Placebo controlled – crossover.

Participant information: 120 women, divided equally into 4 groups.

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

Drug and dosage: Active drugs: Pyridoxine (300 mg/day) in group 1; Alprazolam (0.75 mg/day) in group 2; Fluoxetine (10 mg/day) in group 3; and Propanolol (20 mg/day and 40 mg during the menstrual period) in group 4.

Efficacy outcomes: Fluoxetine in 10-mg doses obtained a mean reduction of 65.4% in symptoms, followed by Propanolol (58.7%), Alprazolam (55.6%), Pyridoxine (45.3%) and placebo (39.4-46.1%).

Conclusion: Fluoxetine in 10-mg doses presented the best results for treating premenstrual syndrome

Trial 1997: Comparative (Herbal/ Vitamin Supplements)

Treatment of premenstrual tension syndrome with Vitex agnus castus controlled, double-blind study versus pyridoxine

Link: https://pubmed.ncbi.nlm.nih.gov/23195474/

Year published: 1997

Trial information: Randomised, controlled trial.

Objective: Determine the efficacy and tolerability of new solid formulation (capsules) of Agnolyt versus pyridoxine in women with PMTS.

Blind/double blind? Double-blind.

Randomised? Yes.

Placebo? No.

Participant information: 175 women with PMTS.

Treatment length: 3 cycles.

Drug and dosage: Vitex agnus castus (VAC): 1 capsule + 1 placebo capsule/day, (90); or Pyridoxine: new solid formulation (capsules) of Agnolyt, 2 capsules/day (85).

Measuring scales: The therapeutic response was assessed using the premenstrual tension syndrome scale (PMTS scale), the recording of six characteristic complaints of the syndrome, and the clinical global impression scale (CGI scale). Upon completion of the trial, efficacy of the treatment was assessed by the physician as well as by the patient.

Efficacy outcomes: On the PMTS scale, treatment with VAC and B6 produced a reduction in score points from 15.2 to 5.1 (-47,4%) and from 11.9 to 5.1 (-48%), respectively. In comparison with pyridoxine, VAC caused a considerably more marked alleviation of typical PMTS complaints, such as breast tenderness, edema, inner tension, headache, constipation, and depression.

Analogous results were obtained with the CGI scale. In both treatment groups, efficacy was rated as at least adequate by more than 80% of the investigators; however, VAC treatment was rated as excellent by 24.5% and pyridoxine treatment by 12.1% of the investigators.

Side-effects assessment: According to the patients' assessment, 36.1% of the cases in the VAC group and 21.3% in the pyridoxine group were free from complaints. Adverse events (gastrointestinal and lower abdominal complaints, skin manifestations and transitory headache) occurred in 5 patients under B6 and in 12 patients under VAC. Serious adverse events were not observed.

Conclusion: The results of the present study confirm the efficacy and safety of Agnolyt capsules in the treatment of PMTS.

1995 Trial: Comparative (Hormone Dosage)

A randomised comparison over 8 months of 100 micrograms and 200 micrograms twice weekly doses of transdermal oestradiol in the treatment of severe premenstrual syndrome

Link: https://pubmed.ncbi.nlm.nih.gov/7632640/

Year published: 1995

Pubmed classification: Clinical trial.

Further trial information: Main: randomised, prospective, comparative study.
Subsidiary: cross-sectional and prospective.

Objective: To determine the efficacy of a 100 micrograms twice weekly dose of Estraderm TTS compared with a 200 micrograms dose in the treatment of severe PMS, and to determine the overall acceptability of the treatment. To determine the serum oestradiol levels produced by the two doses of Estraderm and to discover whether the lower dose suppresses ovulation.

Blind/double blind? Unknown.

Randomised? Yes.

Placebo? No.

Participant information: Women with severe PMS confirmed by prospective daily symptom recording.

Treatment length: Unknown.

Drug and dosage: Estraderm TTS at a dose of either 100 or 200 micrograms twice weekly continuously, with either dydrogesterone 10 mg or medroxyprogesterone acetate 5 mg, from day 17 to day 26 of each cycle.

Measuring scales: Main: Change in total, exponentially smoothed, average maximum score (total-ESAmax) of 10 common premenstrual syndrome symptoms derived from Trigg's trend analysis and patient satisfaction.
Subsidiary: Plasma oestradiol and day 21 progesterone levels.

Efficacy outcomes: Main: No difference in change in total-ESAmax between Estraderm 100 micrograms and 200 micrograms groups. Satisfaction rate of 45% to 57% at eight months.

Subsidiary: 1. Mean (95% CI) oestradiol level of 300 pmol/l (255 to 345) with Estraderm 100 micrograms and 573 (494 to 693) with Estraderm 200 micrograms; 2. Estraderm 100 micrograms suppresses mid-luteal progesterone from a mean (95% CI) of 35.5 (28.4 to 42.7) to 3.4 (2.4 to 4.5).

Side-effects assessment: Main: Greater drop-out rate and greater incidence of side effects attributed to oestrogen occurred in the higher dosage group.

Conclusion: Estraderm TTS 100 micrograms twice weekly is as effective as 200 micrograms twice weekly in reducing symptom levels in severe premenstrual syndrome; but is better tolerated. Estraderm 100 micrograms suppresses ovulation and results in a mean plasma oestradiol level similar to that observed in a spontaneous cycle.