

Nexagen USA

Clinical Study Summary
Jen Fe Next Patch

A synopsis of the 12-week, randomized, double-blind, placebo-controlled study on the effects of the Nexagen USA Jen Fe Next Patch on weight loss, waist circumference, resting metabolic rate and body composition.

In a one year study starting in December 2005, Nexagen USA subjected its Jen Fe Next patch to the most rigorous form of testing in the universe of clinical research—a methodology beyond reproach that is considered by industry experts to be the 'Gold Standard' for scientific evaluation. The 12-week trial was conducted to objectively compare the effects on weight loss, resting metabolic rate and body composition that result when the Jen Fe Next patch is used relative to when it is not used.

The desired result of this study was an objective, quantitative evaluation. It was therefore critically important that only the most highly regarded and reliable of scientific testing methods be used. Anything short of this may have produced a result that would fail to be objective, fail to be scientifically viable or leave some room for doubt about the effectiveness of the Jen Fe Next patch.

It became clear early on that removing all doubt was necessary to the objective at hand, and would require the use of a **randomized, double-blind, placebo-controlled testing environment**. To fully understand the importance of using this specific type of test, it's important to understand the individual elements of the test, what each one means and how each served to fortify the integrity of the testing environment.

A **randomized** sample, as it relates to scientific testing, is one in which every part of the sample group has an identical chance of being selected any time a selection is

made from the entire sample. To be a truly random, the only variable that can be present at the time of selection is chance.

In the case of the Jen Fe trial, random selections were made from an original group of one hundred obese or overweight subjects. The original one hundred subjects were chosen on the basis of their commonalities: all subjects were required to be between the ages of 18 and 75, have a body mass index of 25 or higher and had to be free of any serious chronic disease. This original group of one hundred test subjects also excluded people who had recently taken certain medications, weight loss medications or supplements as well as other medical variables that have been shown to interfere with test results. Once the one hundred original subjects were finalized, completely random selections were made from this group to establish two separate groups of fifty test subjects each. One of these groups would be the 'Placebo' or 'Control' group, and the other would be the 'Jen Fe' or 'Active' group.

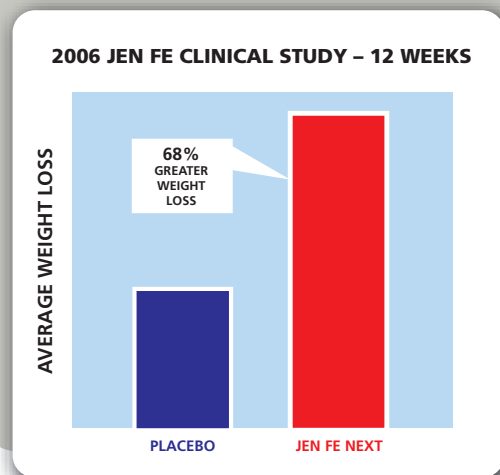
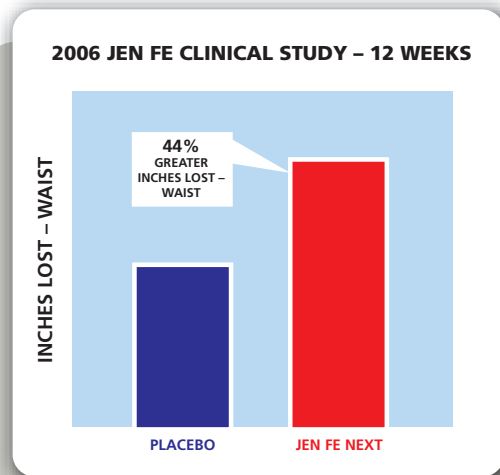
A **placebo-controlled** study is one in which the effects of a given variable, in this case the Jen Fe Next patch, are tested against the effects of a placebo, which is a variable for which there is known to be no effect. In this study, the Jen Fe Next patch was compared to a placebo patch with only adhesive and no active ingredients.

In addition to the placebo control, participants from both groups were given the same instructions for diet and exercise, to further eliminate variations between the two groups. All participants were instructed to follow a balanced diet between 1200 and 1500 calories per day, and to engage in regular exercise (approximately 30 minutes of walking each day).

A **double-blind** study is one in which neither the subjects being tested nor the persons administering testing are aware of the critical aspects of the experiment. The purpose of a double-blind study is to add yet another safeguard to protect the validity of test results. The result is a test that is free from any possible experimenter bias and what is known as the placebo effect (the idea that a test subject receiving a placebo may change their behavior based on what they believe the placebo is doing). Test subjects, both in the Control (Placebo) Group and in the Active (Jen Fe) Group were aware of little more than the fact that they were to follow certain guidelines with regard to diet and exercise, that they must follow specific instructions to apply an adhesive patch each day, and that they must keep a log of their activities related to each. The persons administering the evaluations of the test subjects were not aware of which participants were in the Control Group and which were in the Active Group.

All subjects were assessed a total of four times--once at the onset of the experiment, and at every subsequent 4-week interval for a total of 12 weeks. At each interval, all participants were objectively evaluated with identical equipment on the basis of total weight, body mass index, waist circumference and other key health variables. In addition, all subjects were also screened to ensure that the original criteria for participation had not changed—this included testing for the use of certain medications, pregnancy and other medical variables that could be a source of error in experimentation.

Ultimately, the Jen Fe Next patch passed this test of seemingly insurmountable scrutiny with an exceptional performance, particularly in the categories of weight and inches lost. In fact, when the 12-week assessments of both the Active (Jen Fe) Group and the Control (placebo) group were compared, the difference was remarkable. Jen Fe Next patch users lost an average of 68% more weight than those in the control group and lost an average of 44% more around the waist than those who wore the placebo patch.



In addition to a superb performance in both inches and weight lost, the study data demonstrates that the Jen Fe Next patch does not exude any of the adverse side effects that are common to many weight loss products. In fact, the data indicates that Jen Fe Next had no adverse effect on blood pressure, heart rate or respiratory rate.

In summary, the Jen Fe Next Clinical trial quantifies what so many already subjectively understood—that the Jen Fe Next patch is a very safe and effective product that, when used in combination with proper nutrition and exercise, can affect incredible weight loss results.