Summary of the double-blind study into the effectiveness of BreastFormulation-PS1099 by PS Research

Introduction

Since many women are dissatisfied with their breasts, particularly after having given birth to one or more children, there is a great demand for a safe and affordable way of improving the firmness and size of the breast. BreastFormulation-PS1099 (BF-PS1099) is a natural food supplement, based on hop extracts, soy extract and grain, for which it is assumed that it has an enlarging and firming effect on the breast. Recently an independent research agency, PS Research, carried out a clinical study into the actual effects of BF-PS1099.

Study specifications

Contract Research Organization (CRO): PS Research B.V., Hoofddorp, The Netherlands

Study design: The study was designed as a double-blind, randomized, placebo-controlled study. The study was performed according to ICH-GCP guidelines.

Phase of development: IV

Test product: BreastFormulation-PS1099

Duration of treatment: 24 weeks

Number of participants: 60 planned, 56 enrolled, 39 regularly completed

First participant enrolled: 8 March 2005
Last participant out: 16 November 2005

Inclusion criteria: Pre-menopausal women, aged 18-40 years, breast cup size B or C, no significant co morbidity.

Study methods

56 women took part in this study; all were healthy and not yet in the menopause. At the start of the study a number of measurements were performed, such as body weight, breast volume and breast firmness. Validated methods were used for this, as are described in the medical literature.
Thereafter, for a period of 6 months, the women were given BF-PS1099 or a placebo (a fake preparation that cannot be distinguished from the real agent). At the end of this period and on a number of occasions during this period (after 4, 8, 16 and 24 weeks) the measurements of weight, breast volume and firmness were repeated to determine any possible changes.

Results

Under women who had given birth to at least one child, an increase in breast volume was observed in the BF-PS1099 group (compared with the women from the placebo group); this effect is statistically significant.

In the end 19 women (of whom 9 in the BF-PS1099 group and 10 in the placebo group) with at least one child completed the 6 months' course of treatment.

If this sub-group is taken on its own, we can state that an average increase of +21% in breast volume in the BF-PS1099 group was observed compared to an increase of +8% in breast volume in the placebo group ($p=0.044$[1]). This means an average increase of 50 ml for a woman with cup size B (average volume of 250 ml), through the use of BF-PS1099. We can even expect an average increase of 60 ml for a cup size C (average 300 ml).

Side effects

It is also important to note that during this study no significant side effects of the product were found.

Conclusion

BF-PS1099 is a safe product that can increase the volume of women's breasts. There are also indications of a positive effect on the firmness of the breasts within this same group of women; this is however still not conclusively proven and must be confirmed in additional studies.

Recommendation for further study

Since the study sample was relatively small no hard conclusions could be drawn about other specific subgroups such as for instance women without children. However a number of very interesting observations were made that give reason for further study with a larger number of participants.

Author

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[1] The p-value (a number ranging from 0 to 1) indicates the reliability of the observation. The lower the p-value, the more reliable the observation. If the p-value is lower than 0.05, then this means that the chance that the observation is coincidental, is less than 5%. This is referred to as a "statistically significant" result. If the p-value is around 0.10 or 0.15, then this is considered to be a trend or a strong possibility; additional study is then desirable.