SYNOPSIS

Name of sponsor company : DM Contact Management Ltd., USA
Name of finished product : VigRX Plus capsules
Name of active ingredients: Panax ginseng (Korean Red Ginseng) Serenoa repens (Saw Palmetto) Crataegus rivularis (Hawthorne) Ginkgo biloba Turnera diffusa (Damiana) Tribulus terrestris Erythroxylum catuaba Ptychopetalum olacoides (Muira Puama) Cuscuta chinensis Epimedium sagittatum Bioperine (extract from Piper nigrum fruit)
Title of the study: A triple blind, placebo controlled, randomized study to evaluate the safety and efficacy of VigRX Plus capsules as a dietary supplement to improve erectile function and maintain Male Sexual Health.
Investigators and study centres: **1)Dr. Gaurang Shah** Jivdaya Hospital,Dharmoday bldg, Jivdaya lane, L.B.S. Marg, Ghatkopar (W), Mumbai-86.INDIA.Mob: 9821019432. **2)Dr. R. K. Shimpi** Dept. of Urology,Noble Hospital, 153,Magarpatta City Road, Hadapsar,Pune-411 013. INDIA Mob : 9822059799 **3)Dr. Suresh Patankar** Institute of urology,Survey no. 32/2A, Erandwane, Behind Mehendale garage,Gulwani Maharaj road, Pune-4.INDIA. Mob : 9881256992
Study period: Date of first enrollment: 07/05/2009 Date of last completed: 17th Dec 2009
Phase of study : Therapeutic exploratory

Objectives

Primary objective

To evaluate the efficacy of VigRX Plus capsules as a dietary supplement to improve erectile function as assessed by Erectile function subscale of IIEF Questionnaire (IIEF-A) from baseline to end of treatment as compared to placebo.

Secondary objectives

- To evaluate the efficacy of VigRX Plus capsules as a dietary supplement for Male Sexual Health as assessed by IIEF (Total) (International Index of Erectile Function) questionnaire from baseline to end of treatment as compared to placebo
- To evaluate the efficacy of VigRX Plus capsules as a dietary supplement for Male Sexual Health as assessed by IIEF-B questionnaire (sum of all the subscales of IIEF except erectile function subscale) from baseline to end of treatment as compared to placebo
- To evaluate the impact of VigRX Plus capsules as a dietary supplement for Male Sexual Health as assessed by EDITS questionnaire (Patient & Partner version) as compared to placebo
- To evaluate the safety of VigRX Plus capsules as a dietary supplement for Male Sexual Health from baseline to end of treatment as compared to placebo
- To assess the effect of VigRX Plus on the sperm count, motility, semen volume from baseline to end of treatment.
- To assess the effect of VigRX Plus on Serum testosterone from baseline to end of treatment as compared to placebo

Diagnosis and main criteria for inclusion

1. Male subjects aged between 25-50 years
2. Subject having a monogamous, heterosexual relationship
3. Male subjects with IIEF-A score 11 to 23 & IIEF-B score 21 to 35 at screening visit & baseline visit
4. Subject provides written informed consent and comes for regular follow up

Methodology

75 males between 25-50 years of age were recruited to get 60 completed cases. Subjects with an IIEF erectile function domain score of 11-23 and remaining domains score of 21-35 were eligible for the study. For each subject the study terminated after a maximal period of 84 days from enrollment and included 5 follow up visits. After consenting to participate subjects were put on 15 days wash-out period before being administered the investigational product or placebo. On baseline visit (Day 1), medical history and physical examination were performed, IIEF Total questionnaire was assessed and the trial medications were dispensed. At all the follow-up visits (at an interval of 28 days) each subject was administered a new IIEF (Total) and an EDITS questionnaire. Each subject received another supply of the trial medications during these visits. On Day 28 and Day 84 EDITS questionnaire partner version scores were obtained from partners who consented for the same. Additionally at these visits subjects rated the tolerability of the treatment they received. At the end of treatment investigator's global opinion of therapy and subject's opinion on continuing with the trial medication was obtained.

Number of patients planned: 60 completed cases

Number of patients analysed :75

Test product, dose and mode of administration, batch number

VigRx Plus -2 capsules twice a day with meals for 12 weeks, Batch No:VP01.

Reference therapy: Placebo 2 capsules twice a day with meals for 12 weeks
Batch No: VX01,

Criteria for evaluation:

Primary efficacy evaluation

Improvement in IIEF-A (Erectile function domain of the International Index of Erectile Function) score for erectile function domain as compared to placebo

Secondary efficacy evaluation:

- Increase in total score of quality of sexual life questionnaire-IIEF (Total) as compared to placebo

Secondary efficacy evaluation (continued):

- Improvement in IIEF-B (other than the erectile function domain) score as compared to placebo
- Satisfaction with treatment (EDITS Patient & partner version) as compared to placebo
- Improvement in Semen Analysis Parameters as compared to placebo
- Improvement in Serum Testosterone (Total) levels , as compared to placebo

Safety

Monitoring of adverse events. Clinical examination, Assessment of vitals and laboratory parameters.

Statistical methods

Analysis for safety was done on an intention-to treat population. This included subjects who received at least one dose of treatment post randomization and for whom at least one post baseline measurement was available. Missing data were imputed using last observation carried forward (LOCF) method.

Analysis of efficacy was primarily done on a per protocol data set constituting of subjects completing all the protocol required visits. Changes from baseline in IIEF scores were asessed using analysis of covariance (ANCOVA). Data on EDITS (patient and partner versions) were analysed by independent sample t test. Chi-square test was used to analyse investigators' assessment and subjects, opinion across the two groups. All statistical tests were applied at 5% level of significance.

Results

Efficacy

Treatment with VigRx Plus resulted in a statistically significant increase ($p<0.0001$) of IIEF-A, IIEF-B and IIEF-Total scores as compared to placebo, on Day 84 (end of treatment).In subjects treated with VigRx Plus, mean increases from baseline to end of treatment for IIEF-A, IIEF-B and IIEF-Total were 9, 20.1 and 11.56 respectively. The corresponding increases in the placebo group were 0.62, 1 and 0.68.Treatment satisfaction as assessed by EDITS (patient version) was statistically significantly higher in the VigRx Plus group as compared to placebo on Day 28, Day 56 and Day 84. At the end of treatment, mean EDITS score was 82.31 in the VigRx group and 36.78 in the placebo group.

Results (continued)

Female partners reciprocated the satisfaction levels experienced by their male counterparts treated with VigRx Plus, with the mean EDITS (partner version) score of 69.58 in the VigRx Plus group being statistically greater than that of 25.5 in the placebo group.

There was no statistically significant difference in the sperm count, semen volume and sperm motility between the two treatment groups. Serum Testosterone levels did not change significantly in any of the study groups.

At the end of study, global assessment of therapy by investigator clearly saw a superiority of outcomes in subjects receiving VigRx Plus as compared to those receiving placebo, with statistical significance. Subjects' opinion was also statistically significant in favor of VigRx Plus.

Safety

VigRx Plus and placebo both were safe and well tolerated in the study. Changes in laboratory and vital signs were clinically insignificant. The only serious adverse event reported in this study was when one subject from the VigRx Plus group suffered from infection due to malarial parasite and was subsequently withdrawn from the study.

Conclusion

In conclusion, use of VigRx Plus for twelve weeks was significantly better than placebo in improving erectile function in subjects with sexual dysfunction. It was also significantly superior to placebo in improving the other aspects of sexual health such as libido, intercourse satisfaction, orgasmic function and overall satisfaction. The enhancement of sexual function was endorsed by female partners of subjects receiving VigRx Plus. VigRx Plus was safe and well tolerated in subjects with male sexual dysfunction.