

PROSPECTIVE STUDY OF FERTILAIID[®] VITAMIN IN MEN WITH LOW SPERM QUALITY

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Abstract

Introduction and Objectives: A 90-day, randomized, double-blind, placebo controlled study determined if treatment with the vitamin FertilAid[®] for Men (Fairhaven Health, Bellingham, WA) improved sperm quality in men. **Methods:** Adult males were enrolled with abnormal sperm parameters defined as one or more: low counts, low percentage of motility; or low percentage of normal morphology. Eligible subjects (including no vitamin ingestion within 30 days) provided two baseline (initial) semen samples. Routine semen analysis was performed according to current WHO guidelines (World Health Organization, 1999) to determine: sperm count per ml and per total ejaculate; percent motile sperm and speed of progression for the motile sperm; and strict assessment of sperm morphology. From these parameters the total motile sperm count and total normal-motile sperm counts for each ejaculate were determined. Following analysis of the baseline semen samples, subjects were randomly assigned to FertilAid[®] or placebo. Following the 90 days of vitamin or placebo therapy, subjects again provided two semen samples. The same laboratory performed the initial and final analyses for each man. Statistical analysis was performed using the Mann Whitney U test. **Results Obtained:** No differences existed for sperm parameters between the groups at baseline. A total of 14 subjects completed the trial (initially 10 per treatment were recruited). Eight were randomized to FertilAid[®] and 6 were randomized to placebo. Total normal-motile sperm numbers in the ejaculate improved for men using FertilAid[®] (p=0.05), versus men on placebo. Additionally, the total motile sperm count also showed a tendency towards improvement (p=0.09). Other parameters did not differ between the two groups. **Conclusions:** In spite of the small sample size in this study, significant improvements were found for men taking FertilAid[®], with regards to the total number of normal-motile sperm in the ejaculate. Larger studies should be done to confirm the results seen here. Use of FertilAid[®] by the male partner may improve the ejaculate quality in some men, specifically with regards to the number of normally shaped, motile sperm produced. Funded in part by Fairhaven Health.

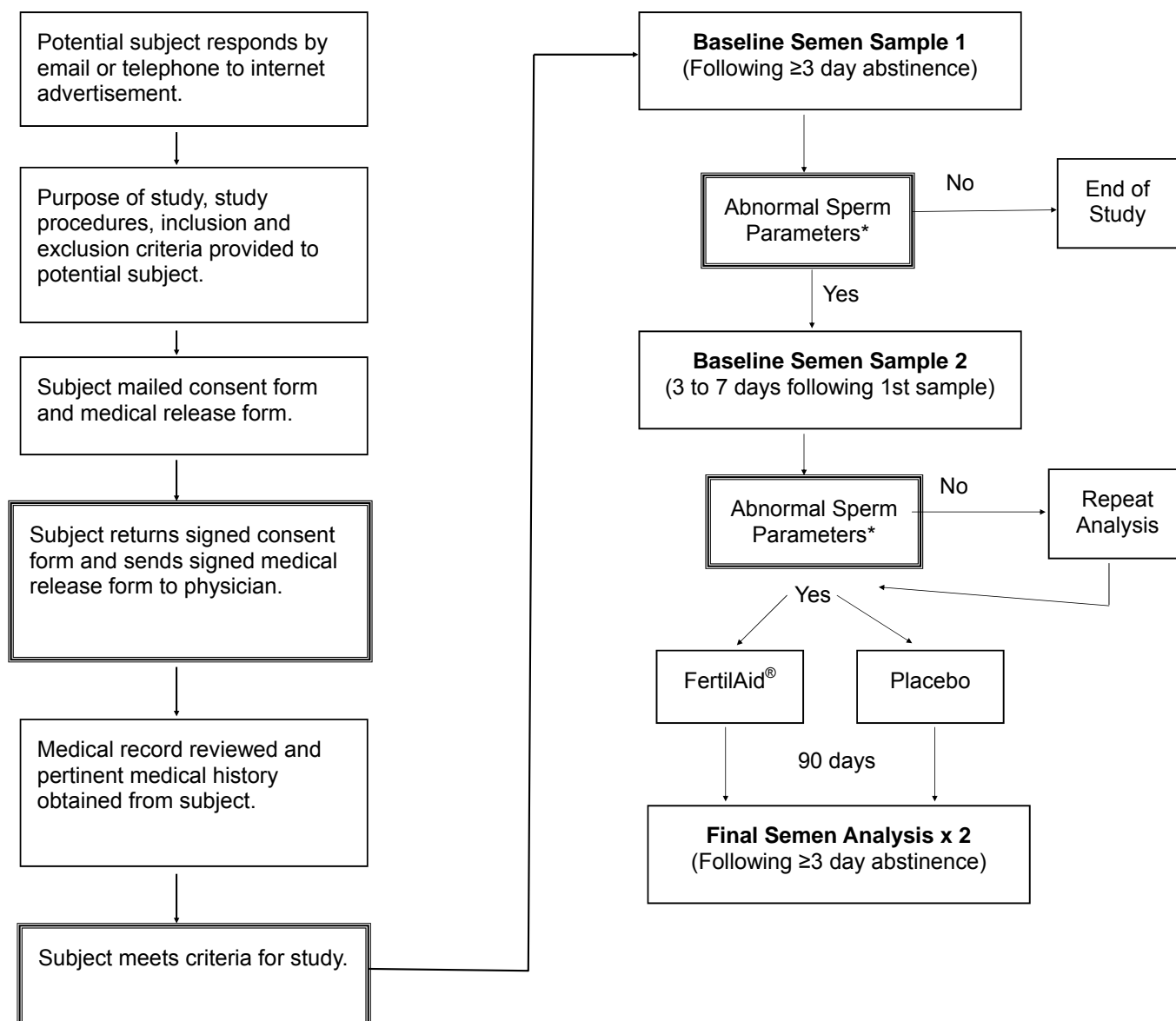
Purpose

The purpose of this trial was to determine whether 90-day treatment with the vitamin FertilAid[®] for Men improves sperm quality, in men with low sperm quality, as compared to placebo treatment.

Study Design

90-day, randomized, double-blind, placebo controlled study.

Subject Recruitment, Screening, Treatment Assignment, and Data Collection:



Participants

Adult, trying-to-conceive men, with abnormal sperm parameters (according to 1999 WHO Guidelines) defined as one or more of the following*:

- abnormally low sperm counts
- low percentage of motile sperm or
- low percentage of normal morphology.

Exclusion Criteria

- Ingestion of any fortified antioxidant vitamin formulation within 30 days prior to enrollment
- Azoospermia
- Active urogenital tract infections
- Diabetes
- Varicocele

Sample Collection and Analysis

Ejaculates were collected by masturbation into a sterile specimen cup either at home or at the laboratory. Samples collected at home were received at the laboratory within 30 minutes of collection. Routine sperm analysis was performed according to current WHO guidelines. The same laboratory performing the initial 2 analyses also performed the final analyses. For each subject, an average outcome for the sperm parameters at each time was determined using the average of the two ejaculates initially and at post treatment

Treatment

Subjects were instructed to ingest 3 capsules of the assigned treatment (FertilAid[®] for Men or matching Placebo) by mouth with 6 ounces of water once each morning. Telephone calls were made at 2-week intervals to assess compliance.

Data Analysis

Because of the variability in reporting methods used by the various laboratories, a non-parametric statistical method was performed to evaluate differences between the treatment and placebo group. The following parameters were analyzed:

- total ejaculate sperm count
- percent motile sperm
- percent forward progression of motile sperm
- total motile sperm count
- percent of sperm with normal morphology and
- total normal-motile sperm count.

Any changes in outcome for the average sperm parameters between the initial and post treatment were scored as: (2) for a parameter increase of 20% or more; (1) for an increase of <20% or >5%; (0) for no change (<5% deviation either way); (-1) for a decrease of <20% or >5%; and (-2) for a decrease of 20% or more. Statistical analysis was performed using the Mann Whitney U test.

Results

Fourteen subjects (age 35.6 ± 9.2 years) completed the 90-day trial. Eight of the 14 subjects were randomized to FertilAid[®] and 6 were randomized to matching Placebo. No significant difference existed for demographics or sperm parameters between the groups at initial analysis.

- When taken together, the overall ejaculate outcome for total normal-motile sperm significantly improved for men using FertilAid[®] (p=0.05), versus men receiving placebo.
- The total motile sperm count in the ejaculate also showed a strong tendency towards improvement (p=0.09) in those receiving FertilAid[®] versus Placebo.
- These differences were due to a higher percentage of men with improvements of 20% or more in their ejaculates (following FertilAid[®] use), for the total normal-motile sperm count and total motile sperm count.
- Individual parameters of overall counts for sperm in the ejaculate, percent motile sperm and percent of sperm with normal shapes did not significantly differ between the two groups.

Conclusion

In spite of the small sample size, significant improvements were found for men taking FertilAid[®] for Men, with regards to the total number of normal-motile sperm in the ejaculate.

These data suggest that larger studies into the effect of this vitamin supplement should be done to confirm the trends seen here. Other studies have also shown the value of vitamin-antioxidant supplements for subfertile men. This may be in part due to the lower levels of endogenous antioxidants found in the semen of subfertile men, which appear to make these men's sperm more susceptible to reactive oxygen species damage, including damage to sperm chromatin.



Ingredient	Amount
Vitamin A (as beta-carotene)	5,000 IU
Vitamin C (ascorbic acid)	250 mg
Vitamin D (as cholecalciferol)	400 IU
Vitamin E (as d-alpha tocopheryl succinate)	150 IU
Vitamin K	80 mcg
Thiamin	1.5 mg
Riboflavin	1.7 mg
Niacin	20 mg
Vitamin B6 (pyridoxal 5-phosphate)	2 mg
Folate	500 mcg
Vitamin B12 (as methylcobalamin)	25 mcg
Pantothenic Acid (d-calcium pantothenate)	10 mg
Iodine (kelp)	150 mcg
Magnesium (magnesium oxide)	120 mg
Zinc (zinc gluconate)	50 mg
Selenium (selenomethionine)	100 mcg
Copper (copper gluconate)	2 mg
Manganese	2 mg
Chromium	120 mcg
Proprietary Blend	875 mg
L-carnitine (as tartrate)	
Maca root (Lepidium meyenii g.)	
Grape seed extract (standardized to 90-95% proanthocyanidins)	
Panax ginseng (standardized to 2.1% ginsenosides)	