

Triple-Blind Randomized Placebo-Controlled Study of the Effect of StemEnhance on Bone Marrow Stem Cell Mobilization¹

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Aim of the study

A triple-blinded, randomized, placebo-controlled study on human subjects was conducted on the effect of AFA extracts on the number of circulating stem cells.

Methods

Consumables

Volunteers were fed one gram of a blend of two AFA extracts (StemEnhance – SE), and a placebo (Ctrl).

Volunteers

A total of 15 healthy volunteers were selected using the following exclusion criteria:

- Under 20 or over 65 years of age
- Pregnancy
- Severe asthma and allergies requiring daily medication
- Any known chronic illness or previous/current venereal disease
- Frequent recreational drug use
- Impaired digestive function (including previous major gastrointestinal surgery).

Upon arrival, the volunteers were seated in quiet areas and instructed to remain quiescent, comfortably sitting in a chair, for one hour. Immediately after drawing the baseline sample, a consumable was provided. The volunteers were instructed to remain quiescent for the whole duration of the experiment. Blood samples were later drawn 30, 60 and 120 minutes after ingestion of the consumable.

Assessment of circulating stem cells

At each time point, 5 ml blood was drawn into heparin, and 2 ml blood was drawn into EDTA. One sample was used to perform a complete blood count (CBC) while the other sample was prepared for immunostaining (CD34, CD45 and CD14) and flow cytometry. Flowcytometry and data analyses were done blindly. Data is expressed as mean \pm SE.

¹ This is a summary of a full-length study report prepared for publication in the peer-review scientific literature.

Results

Consumption of SE led to an increase in the number of circulating CD34+ cells, while consumption of the placebo did not lead to any statistically significant effect.

Since the overall time for the absorption of bioactive compounds, delivery to target organs, and the generation a quantifiable physiological response may be different depending on each volunteer's overall physiology, we calculated the maximum response of SE at any one point in time, within 60 minutes of consumption. We found a $24 \pm 5\%$ increase (median = 27%) in the number of circulating stem cells with SE.

If we include data obtained during a dose study performed in May 2005, the average maximum response raises to $30 \pm 6\%$.

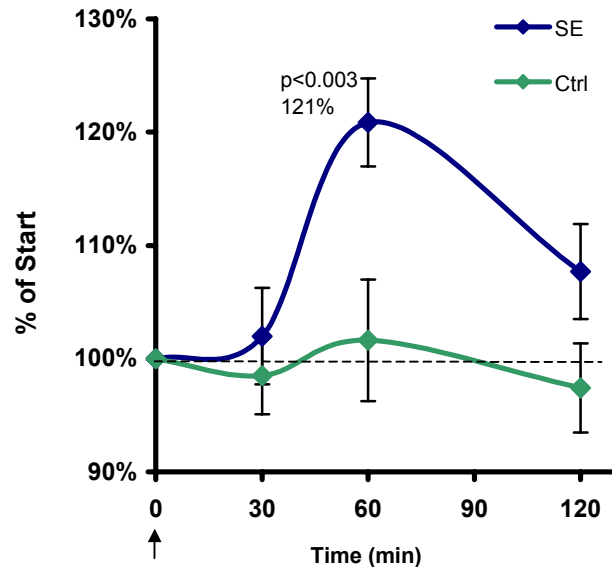


Figure 1. Time course of the number of CD34+ cells in peripheral blood after consumption (arrow) of SE and placebo (Ctrl). Data are expressed as % of starting value. Bars express standard error.

Discussion

This study confirmed that SE is effective at supporting the release of stem cells from the bone marrow, increasing the number of circulating stem cells (CD34+ cells). The data collected show that SE increases the number of circulating stem cells by up to 30%.

Physiological relevance of the observed stem cell mobilization

In this study the average number of lymphocytes was 1,978 per μL and the average proportion of CD34+ cells at time 0 was 0.12%, for an average number of circulating CD34+ cells of 2.4 per μL . An increase of 25% to 30%, as seen in this study, translates to an average increase of 0.7 stem cells per μL , i.e. from 2.4 to 3.1 stem cells per μL . Assuming 5.0 liters of blood, this corresponds to approximately 3.5 million new circulating stem cells. The novelty of the concept of using endogenous release of bone marrow stem cells to support optimal health is paralleled by a scarcity of data linking the magnitude of mobilization with physiological relevance. Nevertheless, data exist to estimate the physiological relevance of putting into circulation 3.5 million new stem cells. Based on various studies (Orlic et al. 2001; Bodine et al., 1994; Bodine et al. 1993; Vanderverde et al., 2005; Valgimigli et al., 2005) one can estimate that one gram of StemEnhance can lead to potentially of up to a few billion somatic cells in target tissues. Therefore the average increase of 25% to 30% obtained with SE in this study is likely to have physiological relevance.

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