



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

by Christian Drapeau, MSc.<sup>1</sup>

## 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).

### Procedure

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. Flow cytometry and data analyses were done blindly. Data is expressed as mean  $\pm$  SE.

## Results

**Consumption of StemEnhance 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. (see figure 1, on the next page)

**[CLICK HERE to securely order the new and enhanced StemEnhance Ultra™ for yourself.](#)**

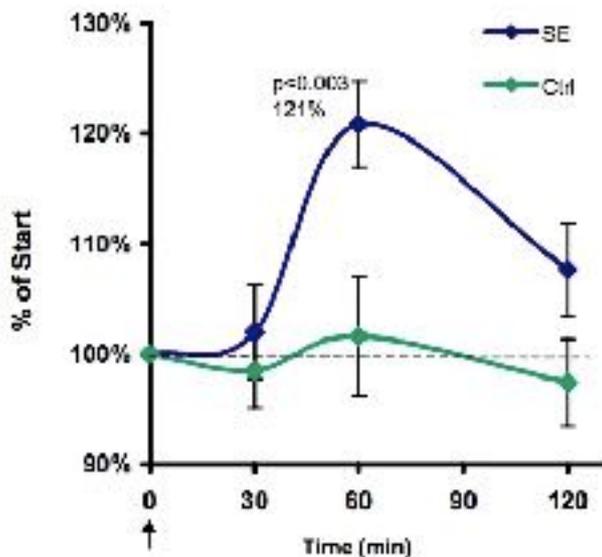


Figure 1. Time course of the number of CD34+ cells in peripheral blood after consumption (arrow) of StemEnhance (SE) and placebo (Ctrl). Data are expressed as % of starting value. Bars express standard error.

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

## 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  $\mu\text{L}$  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  $\mu\text{L}$ . An increase of 25% to 30%, as seen in this study, translates to an average increase of 0.7 stem cells per  $\mu\text{L}$ , i.e. from 2.4 to 3.1 stem cells per  $\mu\text{L}$ . 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.**

## References

- Bodine DM, Seidel NE, Gale MS, Nienhuis AW, and. (1994) Efficient Retrovirus Transduction of Mouse Pluripotent Hematopoietic Stem Cells Mobilized Into the Peripheral Blood by Treatment With Granulocyte Colony-Stimulating Factor and Stem Cell Factor. *Blood*, 84(5): 1482-1491.
- Bodine DM, Seidel NE, Zsebo KM, and Orlic D. (1993) In Vivo Administration of Stem Cell Factor to Mice Increases the Absolute Number of Pluripotent Hematopoietic Stem Cells. *Blood*, 82(2): 445- 455.
- Orlic D, Kajstura J, Chimenti S, Bodine DM, Leri A. & Anversa P. (2003) Bone marrow stem cells regenerate infarcted myocardium. *Pediatr Transplantation* 7 (Suppl. 3): 86–88.
- Orlic D, Kajstura J, Chimenti S, Limana F, Jakoniuk I, Quaini F, Nadal-Ginard B, Bodine DM, Leri A. & Anversa P. (2001) Mobilized bone marrow cells repair the infarcted heart, improving function and survival. *PNAS* 98(18):10344–10349.
- Valgimigli M, Rigolin GM, Cittiati C, Malagutti P, Curello S, Percoco G, Bugli AM, Porta MD, Bragotti LZ, Ansani L, Mauro E, Lanfranchi A, Giganti M, Feggi L, Castoldi G, Ferrari R. (2005) Use of granulocyte-colony stimulating factor during acute myocardial infarction to enhance bone marrow stem cell mobilization in humans: clinical and angiographic safety profile. *Eur Heart J*. Apr 28. Epub.
- Vanderverde S, van Luyn MJ, Tio RA, Harmsen MC. (2005) Signaling factors in stem cell-mediated repair of infarcted myocardium. *J Mol Cell Cardiol*. Jun 28. Epub.

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

**[CLICK HERE to securely order the new and enhanced StemEnhance Ultra™ for yourself.](#)**