

Study Summary

StemForte®

Title	Assessment of the effect of StemForte® herbal supplement on the levels of circulating hematopoietic stem cells in human volunteers
Study Design	Double blind placebo control parallel study
Study Product, Dose, Route, Regimen	StemForte® 3 capsules twice daily to be taken orally for 14 days
Duration of Treatment	14 days
Reference therapy	Placebo
Number of volunteers	Total number of volunteers 20 10 on StemForte® (5 males + 5 females) and 10 on Placebo (5 males + 5 females)
Efficacy Objective	To determine the change in the levels of CD34+, CD45+ and CD133+ in peripheral blood with the use of StemForte® herbal supplement as compared to placebo
Safety Objective	To determine safety of StemForte® herbal supplement
Diagnosis and Main Inclusion Criteria	<ul style="list-style-type: none"> ➤ Healthy adult male and female volunteers in the age group of 18 to 75 years ➤ Volunteers willing to sign the informed consent form
Exclusion Criteria	<ul style="list-style-type: none"> ➤ Patients with anemia [females with Hemoglobin (Hb) < 9 grams/deciliter and males with Hemoglobin (Hb) < 12 grams/deciliter] ➤ Serum glutamic oxaloacetic transaminase (SGOT) and Serum creatinine values twice the upper limit of the normal (ULN) ➤ Volunteers who smoke and consume alcohol or take recreational drugs ➤ Volunteers who suffered with fever or Fu in last one week ➤ History of gastric ulcer or duodenal ulcer ➤ Volunteers on vitamins, nutritional supplement or herbal product since last one month ➤ Pregnant, breast feeding and lactating women ➤ Volunteers taking antibiotic, non-steroidal anti-inflammatory drugs (NSAIDs), or anti-inflammatory drugs within last 7 days ➤ Volunteers allergic to any of the ingredients of the test product ➤ Any co morbid or systemic condition or immunocompromised state that makes the volunteer unfit for participation ➤ Volunteers deemed unfit for the study as per the discretion and clinical judgement of the investigator on a case to case basis

<p>Methodology</p>	<p>The study will be double blind placebo controlled, recruiting male and female volunteers in the ratio of 1:1.</p> <p>Volunteers will take 6 capsules of either StemForte® herbal supplement or Placebo (3 each in the morning and evening per day). Blood samples will be drawn on Day 0 at the following time points:</p> <p>Before first use of the supplement - Baseline blood sample</p> <p>After first dose – at 30 min, 60 min and 120min</p> <p>During the study, blood samples will be drawn on Days 1, 2, 7, 12 and 14. On these days' blood samples will be drawn 1-hour post dose in the morning.</p> <p>The levels of CD34+, 45+ and 133+ will be measured and the levels at End of treatment will be compared with those at Baseline to assess an improvement.</p>
<p>Efficacy Variables</p>	<p>CD 34+, CD 45+ and CD 133+ count by flow cytometry</p>
<p>Safety Variables</p>	<p>Vital parameters Incidence of adverse events and serious adverse events.</p>
<p>Data Analysis Plan</p>	<p>Differences between the groups will be assessed using appropriate tests and P < 0.05 will be considered to indicate statistical significance.</p>

The Development

A stem cell research scientist studied the nutritional needs of bone marrow. He developed a proprietary blend of 24 natural ingredients. StemForte® supplies nourishment to bone marrow, supporting its natural production of healthy new adult stem cells

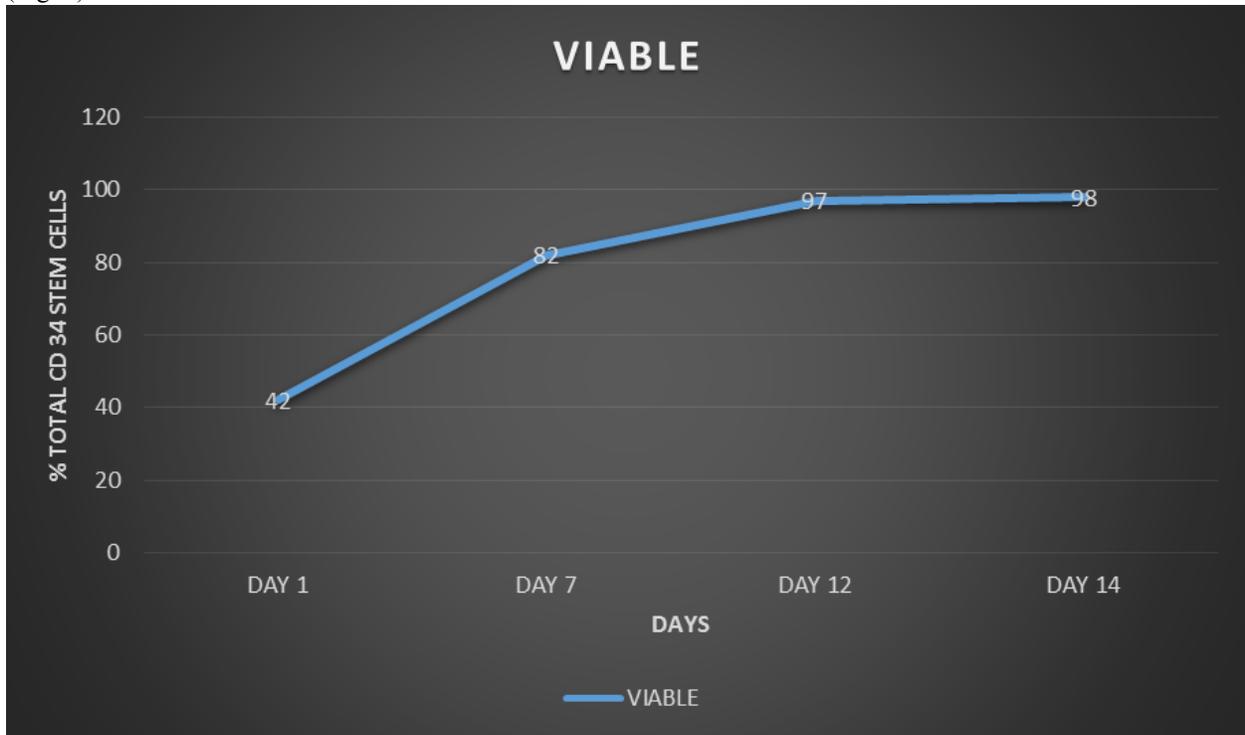
This action is a process where your body's natural renewal system activates due to the proper nutrients being provided to the bone marrow that results in the reproduction and release of stem cells at a faster rate.

Years of scientific research worldwide has shown that a higher number of circulating stem cells is associated with a high level of good health.

Clinical evaluation

In collaboration with a group of other stem cell scientists at major universities and research organizations, scientist conducted a 14-day human clinical pilot study with 20 subjects each taking three capsules in the morning and three at night. Levels of viability of adult stem cells recorded 48% of the released stem cells on the first day, increasing the viability on the seventh day to 82%; registering an improvement of viability in day 12 of 97%. Stem cell levels rose to a 98% increase over a period of two weeks. (Fig. 1)

(Fig. 1)



*Two factors to consider a) The total % of stem cells released b) The viability of stem cells already activated

The same human study was conducted with 20 subjects giving them six capsules each day for 14 days. The average circulating stem cells known as CD 34+ peaked at an increase of 90% after one hour on day one. The average circulating stem cells, known as CD 133+, peaked at an increase of over 86% on day two; likewise showing a 42% release of CD 45+ on day 12 of the study. (Fig. 2)

To identify, isolate and quantify the population of adult stem cells, the marker of choice is CD 34+, which has an important role both in the intercellular adhesion and communication with the extracellular matrix, inducing actin polymerization.

In this logic, these cellular receptors are known as "markers" and have formed groups of differentiation or CD (acronym for Cluster of Differentiation).

This review has grouped the current knowledge concerning the release of adult stem cells that regulates cellular differentiation and development.

As mentioned, adult stem cells that are found in the bone marrow and have proteins on the cell surface, that allow us to identify and quantify through the Cytometry Flow.

Throughout this process, the number of cells circulating in the bloodstream is presented as the most recent element, but the most important part is not the release but the viability of the stem cell. Therefore, the conclusion of this study reveals the release of approximately 20 to 60 million adult stem cells, with the conclusion of 90% viability at the end of the study. Indicating that a high number of adult stem cells circulating and major viability in the body is associated with good health.

(Fig. 2)

STEM CELL TYPE	MAX INCREASE OVER CONTROL 1 HOUR	DAY AT WHICH PEAK OCCURRED
STEM CELL CD 34+	90%	DAY 1
STEM CELL CD 45+	42%	12 DAYS
STEM CELL CD 133+	86%	2 DAYS

CD 34+ Hematopoietic Stem Cells – CD 34+ is a cell surface protein that is present on various cells within the human body. CD 34+ hematopoietic stem cells are sourced from adult bone marrow and have the ability to differentiate into a wide variety of cells; neural cells, muscle cells, liver cells, etc. This has made them a very important topic of adult stem cell research.

CD 45+ Hematopoietic Stem Cells – CD 45+ is a cell surface protein that it is present as a marker on free adult stem cells in our bloodstream.

CD 133+ Hematopoietic Stem Cells – CD 133+ is a cell surface glycoprotein that is also present on various cells within the body, including some hematopoietic stem cells. They are also sourced from bone marrow and have the ability to differentiate into a wide variety of cells.