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Effect of Stem-Kine Food Supplement on Circulating Stem Cells

Submission date	Recruitment status	[ ] Prospectively registered
08/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/02/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/08/2011	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2009-02

Study information

Scientific Title
Effect of Stem-Kine Food Supplement on Circulating Stem Cells: an observational trial

Acronym
ESFSCSC

Study objectives

The food supplement Stem-Kine may cause a modulation of circulating stem cell numbers in healthy volunteers

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of The Center for Improvement of Human Health International, Wichita, Kansas, USA approved on the 29th of July 2009 (ref: 2009-02)

Study design
Observational

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy Volunteers

Interventions
Ingestion of the commercially-available food supplement Stem-Kine:
Two 8 ml blood draws in heparinized Vacutainer tubes are collected by venipuncture before administration of Stem-Kine supplementation (day 0) and at days 1, 2, 7, and 14. Study participants are required to ingest two capsules of Stem-Kine (700mg/capsule) in the morning and two in the evening for 14 days.
Comparison is made pre- and post- treatment all recruited subjects.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Alteration in circulating hematopoietic and endothelial progenitor cells.
Blood samples taken pre-supplementation (day 0), and at days 1, 2, 7, and 14 are analyzed by flow cytometry and colony forming assays

Key secondary outcome(s))
Changes in overall health/mood, based on self reporting

Completion date
01/12/2009

Eligibility

Key inclusion criteria

1. Healthy adults, ages 20-72
2. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Systemic immune-compromised state
2. Ongoing infection or disease conditions
3. Significant abnormalities in biochemistry or complete blood count panels

Date of first enrolment
01/08/2009

Date of final enrolment
01/12/2009

Locations

Countries of recruitment
United States of America

Study participating centre
3100 North Hillside Avenue
Wichita
United States of America
67219

Sponsor information

Organisation
Medistem Inc (USA)

ROR
https://ror.org/03andxb27

Funder(s)

Funder type
Charity

Funder Name
Allan P Markin (Canada) - individual funder

Funder Name
The Aidan Foundation (USA)

Funder Name
The Center For The Improvement Of Human Functioning International (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration