Effect of Stem-Kine Food Supplement on Circulating Stem Cells

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Cohort study

Study setting(s) Other

Study type(s) Other

Participant information sheet Not available in web format, please use contact below to request a patient information sheet.

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 measure

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

Secondary outcome measures

Changes in overall health/mood, based on self reporting

Overall study start date

01/08/2009

Completion date

01/12/2009

Eligibility

Key inclusion criteria

Healthy adults, ages 20-72
 Signed informed consent

Participant type(s) Patient

Age group Adult

Sex Both

Target number of participants 18

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)

Sponsor details 9255 Towne Centre Drive, Suite 450 San Diego United States of America 92122

Sponsor type Industry

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration