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COcoa Supplement and Multivitamin Outcomes Study (COSMOS)

This study is currently recruiting participants. (see Contacts and Locations)

Verified November 2016 by Brigham and Women's Hospital

Sponsor:
Brigham and Women's Hospital

Collaborators:
Fred Hutchinson Cancer Research Center
Mars, Inc.
Pfizer

Information provided by (Responsible Party):
JoAnn E. Manson, MD, Brigham and Women's Hospital

ClinicalTrials.gov Identifier:
NCT02422745

First received: April 17, 2015
Last updated: November 10, 2016
Last verified: November 2016
History of Changes

Purpose

The purpose of this study is to determine whether taking daily, dietary supplements of cocoa extract (containing cocoa flavanols and theobromine from the cocoa bean) and/or a standard multivitamin reduces the risk of developing cardiovascular disease (including heart attack, stroke, coronary revascularization, and cardiovascular mortality) and cancer.

Condition	Intervention	Phase
Cardiovascular Disease Cancer	Dietary Supplement: Cocoa extract Dietary Supplement: Multivitamin Dietary Supplement: Cocoa extract placebo Dietary Supplement: Multivitamin placebo	Phase 4

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Factorial Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Prevention

Official Title: COcoa Supplement and Multivitamin Outcomes Study

Resource links provided by NLM:

MedlinePlus related topics: Dietary Supplements

Drug Information available for: Infuvite Adult Infuvite Pediatric

U.S. FDA Resources

Further study details as provided by Brigham and Women's Hospital:

Primary Outcome Measures:

- The total number of cases of cardiovascular disease (CVD) events. [Time Frame: 5 years] [Designated as safety issue: No]

  Cardiovascular disease events include myocardial infarction (MI), stroke, coronary revascularization procedures and cardiovascular deaths. The total number of cases will include all cardiovascular disease events confirmed by review of discharge summaries, ECG's, laboratory reports, test reports, and death certificates.

- The total number of cases of invasive cancer [Time Frame: 5 years] [Designated as safety issue: No]

  The total number of cases include all diagnoses of invasive cancer confirmed by review of discharge summaries, pathology reports, operative reports, and diagnostic or treatment procedure reports, including both inpatient and outpatient procedures.

Estimated Enrollment:	18000
Study Start Date:	June 2015
Estimated Study Completion Date:	October 2020
Estimated Primary Completion Date:	March 2020 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Cocoa extract + multivitamin	Dietary Supplement: Cocoa extract 2 capsules each day containing a total of 600 mg cocoa flavanols, including 80 mg (-)-epicatechin, and 50 mg theobromine Dietary Supplement: Multivitamin Multivitamin
Active Comparator: Cocoa extract + multivitamin placebo	Dietary Supplement: Cocoa extract 2 capsules each day containing a total of 600 mg cocoa flavanols, including 80 mg (-)-epicatechin, and 50 mg theobromine Dietary Supplement: Multivitamin placebo Multivitamin placebo
Active Comparator: Cocoa extract placebo + multivitamin	Dietary Supplement: Multivitamin Multivitamin Dietary Supplement: Cocoa extract placebo Cocoa extract placebo
Placebo Comparator: Cocoa extract placebo + multivitamin placebo	Dietary Supplement: Cocoa extract placebo Cocoa extract placebo Dietary Supplement: Multivitamin placebo Multivitamin placebo

Hide Detailed Description

Detailed Description:

The COcoa Supplement and Multivitamin Outcomes Study (COSMOS) is a randomized clinical trial of cocoa extract supplement (containing a total of 600 mg/d flavanols, including 80 mg. (-)-epicatechins), and a standard multivitamin supplement to reduce the risk of cardiovascular disease and cancer among women aged 65 years and older and men aged 60 years and older.

Women will be recruited among active Women's Health Initiative (WHI) Extension Study participants, and men will be recruited among non-randomized respondents to the VITamin D and OmegA-3 Trial (VITAL). Women who responded but were not randomized into VITAL will also be included as well as other women and men who express interest in research being conducted at Brigham and Women's Hospital.

Several small randomized trials have demonstrated benefits for cocoa flavanols on intermediate outcomes, including blood pressure, lipids, insulin sensitivity, and flow-mediated vasodilation. For multivitamins, a prior large-scale randomized trial in middle-aged and older men showed a significant reduction in cancer, but comparable trial data in women are lacking. For both interventions, a large-scale clinical trial such as COSMOS could have major clinical and public health implications.

Eligible participants will be assigned by chance (like a coin toss) to one of four groups: (1) daily cocoa extract and multivitamin; (2) daily cocoa extract and multivitamin placebo; (3) daily cocoa extract placebo and multivitamin; or (4) daily cocoa extract placebo and multivitamin placebo. Participants have an equal chance of being assigned to any of these four groups and a 3 out of 4 chance of getting at least one active agent.

Participants in all groups will take three pills each day: two capsules that contain either cocoa extract or cocoa extract placebo, and one tablet that contains either multivitamin or multivitamin placebo. Participants receive their study pills in convenient calendar packs via U.S. mail.

Participants also will be asked to complete short mailed questionnaires each year. The questionnaires ask about health; lifestyle habits, such as diet, physical activity, and smoking; use of medications and dietary supplements; family history of illness and new medical diagnoses. Occasionally, participants may receive a phone call from study staff to collect information or clarify responses on the questionnaires.

At baseline, approximately 6,000 COSMOS participants will provide optional blood and urine samples to determine whether the study agents significantly change biomarkers and other risk factors related to cardiovascular disease and cancer. Selected participants will either have specimens collected through mailed specimen collection kits that are returned by the participant, or have blood, urine, blood pressure, and anthropometric measurements collected by technicians from Examination Management Services, Inc. (EMSI), a national clinical services provider. A subgroup of those who provide baseline specimens and measurements will be asked to provide follow-up samples and measurements.

At baseline and year 2 of the trial, approximately 500 participants living within driving distance of Boston, Massachusetts will provide additional

measurements from in-clinic study visits at the Clinical and Translational Science Center (CTSC) of Brigham and Women's Hospital. These visits will include cognitive function assessments, anthropometrics, physical function assessments, blood pressure and other measurements.

At baseline and after each year of follow-up, approximately 4,000 COSMOS participants will complete web-based assessments of cognitive function. Over the course of the trial, participants will complete up to 4 assessments, each of which takes approximately 25 minutes to complete.

Eligibility

Ages Eligible for Study:	60 Years and older (Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

1. Women ≥ 65 years of age participating in the WHI Extension Study. If fewer than 12,000 women from WHI agree to participate, additional women aged ≥ 65 years who were contacted for but not randomized into the VITAL trial will also be included.
2. Men ≥ 60 years of age who were contacted for but not randomized into the VITAL trial.
3. Other women ≥ 65 years of age and men aged ≥ 60 years of age who express interest in research being conducted at Brigham and Women's Hospital.
4. Willing to participate, as evidenced by providing informed consent and completing all required baseline forms.

Exclusion Criteria:

1. History of myocardial infarction or stroke.
2. Diagnosed with invasive cancer other than non-melanoma skin cancer in the last 2 years prior to enrollment.
3. Any serious illness that would preclude participation and/or completion of the trial, including the diagnosis of kidney failure and current dialysis treatment.
4. Taking cocoa extract or multivitamin supplements and not willing to forego use during the trial.
5. Taking total supplemental vitamin D > 1,000 IU/day and not willing to forego use during the trial.
6. Taking total supplemental calcium > 1,200 mg/day and not willing to forego use during the trial.
7. Extreme sensitivity to caffeine.
8. Consume < 75% of the expected number of both types of supplements during the run-in phase.
9. Unable to communicate in English due to language barrier or mental incapacity.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02422745

Contacts

Contact: Project Coordinator 1-800-633-6913 cosmostrial@partners.org

Locations

United States, Massachusetts

Brigham and Women's Hospital **Recruiting**
Boston, Massachusetts, United States, 02215

United States, Washington

Fred Hutchinson Cancer Research Center **Recruiting**
Seattle, Washington, United States, 98109
Principal Investigator: Garnet L. Anderson, PhD

Sponsors and Collaborators

Brigham and Women's Hospital

Fred Hutchinson Cancer Research Center

Mars, Inc.

Pfizer

Investigators

Principal Investigator: JoAnn E. Manson, MD Brigham and Women's Hospital

More Information

Responsible Party:	JoAnn E. Manson, MD, Principal Investigator, Brigham and Women's Hospital
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Keywords provided by Brigham and Women's Hospital:
Cocoa extract multivitamins cardiovascular disease cancer

Additional relevant MeSH terms:
Cardiovascular Diseases

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