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The effect of a multivitamin and mineral supplement on the common cold

Submission date
09/12/2018

Recruitment status
No longer recruiting

Registration date
03/01/2019

Overall study status
Completed

Last Edited
17/02/2021

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Viral upper respiratory infections (for example colds, coughs, throat infections, influenza) can have a serious impact on health and also result in millions of days lost from employment and education. This study aims to investigate whether taking a vitamin and mineral supplement can reduce the occurrence, duration and severity of common cold symptoms.

Who can participate?
Adult males and females aged 18 to 65 years except those who are smokers, pregnant, breast feeding, have adverse effects to vitamins and minerals, gastrointestinal surgery, immune deficiency or suppression, inflammatory bowel disease, malabsorption syndromes, gastrointestinal dysfunction, or current use of drugs for rheumatoid arthritis that suppress the immune system

What does the study involve?
Participants will randomly be divided into two groups. One group will take the "active" multivitamin and mineral supplement; the other group will take a "blank" caplet that looks identical to the active multivitamin and mineral supplement. The study will be blinded, which means that no one will know who is taking either the active or blank caplet. The study runs for 12 weeks during the months of January, February and March. Every Monday during the 12-week interval participants will receive an email requesting whether during the past week they developed symptoms of the common cold. Those who acknowledge symptoms of a cold, will be asked to answer additional questions about specific symptoms, how long they lasted and how severe their symptoms were. Responses to the email questionnaires will be maintained in a secure, confidential electronic file at the University of Washington. At the conclusion of the 12-week study period, researchers will analyze the information gathered and determine whether the multivitamin and mineral supplement meaningfully reduced the frequency, duration and severity of common cold symptoms.

What are the possible benefits and risks of participating?
Generally, side effects from vitamins and minerals are mild and unlikely if an appropriate amount is taken. In this study, the amounts of vitamins and minerals in the supplement are lower than the amounts expected to cause side effects. As with any research-stage drug, there is a

possibility of unknown side effects. Throughout the study, the investigators will regularly ask participants about side effects and investigate them accordingly. Side effects will be reported to the CHI Franciscan Health Investigational Review Board/Medical Research Evaluation Committee. To avoid the possible effects of interfering substances or problems with intestinal absorption, the formula used in this study is gluten-free, free of genetic modified organisms (non-GMO), vegetarian, nut-free, free of known interfering substances (such as citrate, glycine, tartrate, palm oil and cotton seed oil), free of artificial sweeteners. Women who are pregnant or breast feeding are not eligible to participate in this study.
Benefits include the potential for decreased frequency, duration and severity of the common cold during the study period. Participation could lead to improved treatments for the common cold.

Where is the study run from?
Community Health Care, Tacoma, WA (USA)

When is the study starting and how long is it expected to run for?
June 2015 to May 2017

Who is funding the study?
Community Health Care, Tacoma, Washington provided the majority of funding.
Dr James Lenhart provided donated personal funds due to budget shortfalls. This financial participation was declared prospectively to the IRB and Community Health Care administration to mitigate conflict of interest.

Who is the main contact?
James G. Lenhart, MD, FAAFP, MPH
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

Study information

Scientific Title
The efficacy of a compounded micronutrient supplement on the incidence, duration and severity of the common cold: a randomized, double-blinded placebo- controlled trial

Study objectives
Regular consumption of an immune system targeted micronutrient supplement decreases the incidence, duration and severity of common cold symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Franciscan Health System Medical Research Evaluation Committee, 01/10/2015
2. Franciscan Health System Medical Research Evaluation Committee, 23/08/2016, ref: CHC012016

Primary study design
Interventional

Study design
Randomized double-blinded placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Common cold

Interventions
Study participants were randomized into two groups using REDCap. One group consumed the active immune system targeted multivitamin and mineral micronutrient supplement, while the other group consumed a micronized cellulose placebo with physical characteristics identical to the active caplet. A survey instrument designed to identify and capture critical data was developed and integrated into the Research Electronic Data Capture (REDCap) software to enhance study subject selection, inclusion/exclusion criteria, randomization, blinding, data capture, adverse events and data analysis.

Participants were instructed to take their assigned caplet daily for 12 weeks and to consume no other multiple vitamins or minerals during the study periods. Caplets were administered orally. The participants were followed up for 18 months.
The ingredients in the multivitamin and mineral supplement were:
Vitamin A: 2,500 IU as 50% retinol (retinyl palmitate) and 50% beta-carotene
Vitamin C: 1000 mg as L-ascorbic acid
Vitamin D: 2,000 IU as cholecalciferol (vitamin D3)
Vitamin E: 30 IU as alpha-tocopherol
Vitamin B6: 2 mg as pyridoxine hydrochloride

Vitamin B12: 30 µg as cyanocobalamin
Folate: 400 µg as folic acid
Zinc: 15 mg as zinc acetate
Selenium: 70 µg as sodium selenite
Copper: 900 µg as copper gluconate

Intervention Type
Supplement

Primary outcome(s)
Odds of developing an upper respiratory infection (URI) using a mixed-effects logistic regression model to account for longitudinal measurements over the 12 follow-up time points for each participant. REDCap software electronically captured all data. Participants were emailed REDCap embedded survey instruments weekly beginning the first Monday in January and for 12 consecutive weeks following during the months of January, February and March in both 2016 and 2017.

Key secondary outcome(s)
Incidence, duration, and severity of specific symptoms: sore throat, headache, runny nose, cough, congestion, aches and fever.
Participants were emailed REDCap embedded survey instruments weekly beginning the first Monday in January and for 12 consecutive weeks following during the months of January, February and March in both 2016 and 2017. A mixed-effects logistic regression framework was utilized to assess secondary outcome measures.

Completion date
01/05/2017

Eligibility

Key inclusion criteria
Aged 18 to 65 years

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
259

Key exclusion criteria
1. Planning pregnancy
2. Pregnant
3. Breastfeeding
4. Malabsorption syndromes
5. Celiac disease
6. Inflamatory bowel disease
7. Connective tissue disease
8. Immune deficiency
9. Immune suppression
10. History for intestinal surgery includiing bariatric surgery
11. Kidney disease
12. Liver disease
13. Histroy for cancer
14. History for chemotherapy
15. Utilization of disease modifying anti-rheumatoid medications or similar biologics
16. Use of proton pump inhibitors
17. Cigarette smokers

Date of first enrolment
01/09/2015

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
United States of America

Study participating centre
Community Health Care
1202 Martin Luther King Way
Tacoma, Washington
United States of America
98405

Sponsor information

Organisation
Community Health Care

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Community Health Care

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Bryan Comstock (Senior Statistician at University of Washington School of Public Health) at bac4@uw.edu.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/08/2020	17/02/2021	Yes	No