AquADEKs-2: Effects of an antioxidant-enriched multivitamin on inflammation and oxidative stress in people with CF (AquADEKs-IP-12)

Summary

This study evaluated the effects of an antioxidant-enriched multivitamin supplement on inflammation. This study was for people with CF who are pancreatic insufficient.

Participants were randomized to receive an antioxidant-enriched multivitamin (AquADEKS-2 group) or a control multivitamin without antioxidant enrichment for 16 weeks of treatment.

Specimen Information

Status: Specimens are Available

The purpose of this randomized, controlled study was to evaluate the effects of a modified formulation of AquADEKs® (AquADEKs-2) on markers of inflammation, antioxidant levels, and oxidative stress. Plasma, serum and sputum will be banked.

Visit #	Time From Baseline	Specimens Collected
2	+0 Days	EDTA plasma, Serum
4	+16 Weeks	EDTA plasma, Serum

Study Design

Study Type?	Interventional
Randomized Study?	Yes
Placebo Controlled?	No
Length of Participation	20 Weeks
Number of Study Visits?	4

Additional Information

Phase?	Phase Two
Study Sponsor?	Sagel, Scott
Study Drugs?	AquADEKs-2

Eligibility

Age	10 Years and Older
Mutation(s)	No Mutation Requirement
FEV1% Predicated	40 to 100%
PA Status	Not Applicable
Other	

Study Results

WHAT WE LEARNED:

This study found that participants being treated with AquADEKs-2 did not have significant reduction in respiratory inflammation when compared with the control multivitamin group. AquADEKs-2 was well-tolerated.

PRIMARY FINDINGS:

EFFECTIVENESS:

This study was conducted between September 2013 and June 2015. Of the 73 participants enrolled in the study, 36 were randomized to the AquADEKS-2 group (antioxidant-enriched multivitamin) and 37 to the control multivitamin group. A total of 69 participants completed the study (AquADEKs-2= 34 and control multivitamin= 35).

The primary efficacy endpoint of this study was to measure the change in sputum myeloperoxidase levels between the two groups. Sputum myeloperoxidase is a measure of respiratory inflammation. This study did not meet its primary endpoint as there was no difference in sputum myeloperoxidase levels between the AquADEKs-2 group and the control group at week 16.

SAFETY:

The adverse event profile was similar for both the AquADEKs-2 group and control multivitamin group.

CITATION:

Am J Respir Crit Care Med,DOI 10.1164/rccm.201801-0105OCE-publish ahead of print

For more information about the results of this study and where it was conducted, visit ClinicalTrials.gov.