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.

<table>
<thead>
<tr>
<th>Visit #</th>
<th>Time From Baseline</th>
<th>Specimens Collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>+0 Days</td>
<td>EDTA plasma, Serum</td>
</tr>
<tr>
<td>4</td>
<td>+16 Weeks</td>
<td>EDTA plasma, Serum</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>10 Years and Older</th>
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</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Mutation(s)</strong></td>
<td>No Mutation Requirement</td>
</tr>
<tr>
<td><strong>FEV1% Predicated</strong></td>
<td>40 to 100%</td>
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<tr>
<td><strong>PA Status</strong></td>
<td>Not Applicable</td>
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<tr>
<td><strong>Other</strong></td>
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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.