The Effect of Nopalea™, a Nutritional Supplement Containing Cactus Fruit Juice, on C-Reactive Protein Levels in Healthy Adults Assessed using a Randomized, Double-Blind, and Controlled Experimental Design

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Abstract

Objective:
This study was developed to investigate the anti-inflammatory effects of a commercial product (Nopalea™) containing Prickly Pear Cactus Fruit Juice in 286 healthy adults. The research method employed was a double blind, placebo controlled, and time-series design with C-Reactive Protein (CRP) serving as a marker for inflammation.

Protocol:
Inclusion criteria:
- Live within traveling distance of the research and blood drawing centers.
- Access to a telephone in their residence.
- Between 35 and 75 years of age.
- Must sign an informed consent form.
- Must have a stable blood CRP level.
- Has unstable angina.
- Diagnosed with type I or II Diabetes.
- Diagnosed with depression.
- Has had surgery within 30 days.
- On hormone replacement therapy or other medications.
- Currently taking anti-inflammatory medications.
- Currently ingesting Nopalea™ or another approved advertisement.

Exclusion criteria:
- Currently ingesting Nopalea™.
- Pregnant, planning to become pregnant, or nursing a child.
- Currently taking anti-inflammatory medications.
- On hormone replacement therapy or other medications.
- Diagnosed or demonstrates symptoms consistent with congestive heart failure.
- Has had surgery within 30 days.
- Has unstable angina.
- Had a stroke within the last six months.
- Clinically overt peripheral vascular disease.
- Diagnosed or demonstrates symptoms consistent with congestive heart failure.
- Subjects were required to return to the trial center to obtain blood samples at eight weeks and 12 weeks following implementation of the protocol.

Materials & Methods

Design:
A total of 286 men and women, between 35-75 years of age, were recruited, screened, and randomly assigned to an experimental group (145 subjects) and a placebo group (141 subjects). All participants were recruited via IRB-approved advertisement.

Participants were required to attend an orientation seminar. At this time, a blood sample was obtained to establish baseline CRP levels. Subjects were provided with either Nopalea or apricot juice and instructed to ingest six fluid ounces of fruit juice daily.

Subjects were required to return to the research and blood drawing centers.

Results & Conclusions

Results:
A total of 286 subjects began the study, including 145 and 141 participants assigned to the experimental group and control group, respectively. A total of 18 people dropped out for various reasons, 16 from the apricot group and two from the Nopalea group.

Blood concentrations of CRP in participants ingesting Nopalea were reduced by an average of 20.9% over a period of eight weeks. This effect diminished with time in that CRP levels were reduced by only 10.5% compared to baseline at 12 weeks (see Table 1). At both eight and 12 week assessments, these reductions were statistically significant (p<0.05).

Blood concentrations of CRP in participants ingesting apricot juice were reduced by an average of 7.9% over a period of eight weeks (see Table 2). By 12 weeks, this effect diminished and CRP levels were only 3.1% less than those at baseline. At both eight and 12 week assessments, these reductions were not statistically significant (p>0.05).

Conclusions:
This study demonstrated that eight week supplementation with 6oz of Nopalea results in a statistically significant decrease in CRP in healthy subjects with levels of CRP under 3mg/L.

The results seem to support the potential use of the Nopalea product as a modulator of inflammation in healthy individuals that allows for good compliance. However, it remains uncertain to what degree and for what duration this fruit juice-induced reduction in inflammation has, long term, on morbidity and mortality.