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ASPEN STUDY

A 16-Week Open-Label Trial Evaluating the Safety and Effects of ASEA Redox Supplementation on Inflammatory and Antioxidant Biomarkers in Healthy Adults

Summary of studies conducted by:
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STUDY HIGHLIGHTS

- Clinical chemistry, lipid profiles, hematology, and metabolic markers remained within normal reference ranges throughout the study.
- No clinically significant changes were observed in cholesterol, glucose, liver function, kidney function, or blood cell counts.
- Serum sodium and chloride levels remained stable and within normal ranges for all participants.
- The supplement was well tolerated, and no adverse events were reported.
- Circulating levels of the inflammatory cytokines IL-1β and IL-6 decreased in a subset of participants over the study period.
- Total glutathione (GSH) levels increased over 16 weeks, suggesting enhanced antioxidant capacity.
- These findings indicate that daily supplementation was safe in healthy adults and was associated with changes in selected inflammatory and antioxidant biomarkers.

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Introduction

Redox signaling refers to the cellular communication processes mediated by reactive molecules such as reactive oxygen species (ROS), which are generated during normal metabolic activity. Although historically viewed as damaging byproducts of oxidative metabolism, ROS are now recognized as important signaling molecules that regulate a variety of physiological pathways (1).

These signaling mechanisms influence numerous biological processes, including immune regulation (2), cardiovascular function (3), neural signaling (4), mitochondrial energy metabolism (5), hepatic detoxification (6), and tissue repair (7). Through the modulation of transcription factors such as Nrf2 and NF-B, redox signaling helps coordinate cellular responses to oxidative stress, inflammation, and metabolic demands (8). When redox balance is maintained, these pathways support cellular adaptation and homeostasis. However, dysregulation of redox signaling has been associated with chronic inflammation, cellular damage, and age-related disease processes (9).

One major regulatory pathway involved in cellular antioxidant defense is the NRF2 signaling pathway, which is activated in response to oxidative stimuli. Upon activation, NRF2 translocates to the nucleus and induces expression of genes encoding antioxidant enzymes and cytoprotective proteins. This response often follows a hormetic pattern, in which moderate oxidative stimuli trigger beneficial adaptive responses, while excessive oxidative stress can cause cellular damage (10–12).

Changes in inflammatory cytokines such as interleukin-1 beta (IL-1ß) and interleukin-6 (IL-6), along with antioxidant molecules such as glutathione (GSH), provide measurable indicators of these redox-regulated biological processes (13–17). Increased antioxidant capacity may reduce oxidative stress and modulate inflammatory signaling pathways. The present study therefore evaluated whether supplementation with ASEA Redox Cell Signaling Supplement influences these biomarkers in healthy adults.

OBJECTIVE

The objective of this study was to evaluate the safety and biomarker effects of daily consumption of 8 fl oz of ASEA Redox Cell Signaling Supplement (ARS) over a 16-week period in healthy adults aged 21 – 55. Outcomes included changes in inflammatory markers, antioxidant status, lipid profiles, glucose metabolism, and other standard clinical chemistry parameters.

STUDY DESIGN

Study Design

This open-label clinical study enrolled 30 healthy adults aged 21 – 55, with equal representation of male and female participants. The study included screening and baseline assessments, followed by evaluation visits at Day 60 and Day 120, and a final safety follow-up.

Participants consumed 4 fl oz of ARS twice daily (morning and afternoon) for 16 weeks. Subjects were instructed to maintain their normal diet and lifestyle throughout the study to minimize external influences on measured outcomes.

At each assessment point, clinical chemistry panels, lipid profiles, hematology markers, inflammatory cytokines, and antioxidant markers were measured.

Basic Protocol

This IRB-approved, open-label study was conducted in Orem, Utah to evaluate the safety of ASEA Redox Supplement (ARS) in healthy adults aged 21 – 55 without pre-existing medical conditions. Gender stratification enabled comparative analysis between male and female participants. Each subject ingested 4 fluid ounces of ARS twice daily for 16 weeks (morning and afternoon on an empty stomach), with all participants enrolled for the full study duration.

Safety Evaluation

Safety was assessed through laboratory chemistry and hematology tests conducted at baseline (Day 0), mid-study (Day 60), and end-of-study (Day 120) following twice-daily ingestion of 4 fluid ounces of ARS in adults aged 21 – 55. The principal investigator reviewed results at each time point, and both serious and non-serious adverse events were monitored throughout, with participants maintaining diaries to document any side effects. This comprehensive approach ensured robust safety oversight and confirmed the supplement's tolerability during the study.

Testing Product

ARS is a scientifically formulated liquid supplement containing deionized water and sodium chloride, with each 4-ounce serving providing approximately 125 mg of sodium and 193 mg of chloride. Using ASEA's patented electrochemical process, these ingredients are converted into active redox signaling molecules that support cellular communication and antioxidant production. Manufactured in NSF-certified, FDA-registered facilities, ARS is designed to enhance the body's own antioxidant defenses through improved cellular signaling, and its safety and efficacy have been validated in independent clinical studies.

Efficacy Analysis

Descriptive and frequency-based statistical analyses were performed on both quantitative and qualitative safety data, comparing laboratory results at 60 and 120 days to baseline and established reference ranges. This approach ensured a thorough assessment of participant safety and allowed for evaluation of the supplement's impact on inflammatory markers, providing a comprehensive view of both tolerability and efficacy over the course of the study.

RESULTS

Health Parameters Related to General Human Body Physiology

During the study, the evaluation of ASEA Redox effects across various health parameters (Table 1) showed that none of the parameters shifted outside their healthy ranges, as detailed below:

- General function markers such as calcium, sodium, potassium, chlorine, carbon dioxide, total protein, globulin, A/G protein ratio, and anion gap related to blood pH remained stable.
- Similarly, lipid panel results, including triglycerides, cholesterol, direct LDL, VLDL, HDL, and cholesterol/HDL ratio, showed no notable alterations.
- Blood sugar levels, measured by glucose and HGB A1C, were unaffected.
- Heart health indicators, homocysteine and CRP, did not exhibit significant changes.
- Kidney function parameters, including blood urea nitrogen, creatinine, EGFR, and the ratio of BUN/creatinine, remained consistent.
- Liver function tests, such as total bilirubin, AST, ALT, albumin, and alkaline phosphatase, showed no significant variations.
- Hematology results, encompassing white blood cells, red blood cells, HGB, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, red cell distribution width, platelet count, mean platelet volume, granulocyte percentage in WBC, neutrophils percentage in WBC, lymphocytes percentage in WBC, monocytes percentage in WBC, eosinophil percentage in WBC, basophils percentage in WBC, immature granulocytes, neutrophils, lymphocytes normal levels, monocytes, eosinophils, basophils, nucleated red blood cells, and percentage of nucleated red blood cells, also showed no significant changes.

Table 1

Analysis of Different Physiological Parameters

Interpretation considering established reference ranges (all stayed within range).

General Function	Hematology
Calcium	White Blood Cells
Sodium	Red Blood Cells
Potassium	HGB
Chlorine	Hematocrit
Carbon Dioxide	Mean Corpuscular Volume
Total Protein	Mean Corpuscular Hemoglobin (MCH)
Globulin	MCH Concentration
A/G Protein Ratio	Red Cell Distribution Width
Anion Related to Blood pH (Gap)	Platelet Count
Lipid Panel	Mean Platelet Volume
Triglycerides	Granulocyte % in WBC
Cholesterol	Neutrophils % in WBC
Direct LDL (decrease is good)	Lymphocytes % in WBC
HDL (increase is good)	Monocytes % in WBC
Cholesterol/HDL	Eosinophil % in WBC
Blood Sugar	Basophils % in WBC
Glucose	Immature Granulocytes
HGB A1C	Neutrophils
Kidney Function	Lymphocytes Normal Levels
Blood Urea Nitrogen	Monocytes
Creatinine	Eosinophils
EGFR (Estimated Glomerular Filtration Rate)	Basophils
Ratio of BUN/Creatinine	
Liver Function	
Total Bilirubin	
AST	
ALT	
Albumin	
Alkaline Phosphatase	

This comprehensive analysis indicated the supplement did not have an adverse impact on these health parameters in the study participants. All clinical chemistry, metabolic, and hematology values remained within normal reference ranges for all participants throughout the study. No adverse shifts or out-of-range results were observed in any measured parameter, indicating the supplement was well-tolerated and did not negatively impact general health markers.

Table 2

Analysis of Various Inflammatory Markers

Inflammatory Markers	Average Summary		
	% Change from Baseline to Day 60 (*)	% Change from Baseline to Day 120 (*)	% Change from Day 60 to Day 120 (**)
Interleukin 1 Beta	16.59% decrease	88.97% decrease	86.78% decrease
Interleukin 6	2.64% decrease	11.51% decrease	9.64% decrease
Total Glutathione	10.93% increase	14.43% increase	3.15% increase

(*) All percentage changes were calculated relative to baseline values (Day 0); (**) Percentage changes reflect comparison between Day 60 and Day 120 only. For all individuals, changes remained within normal ranges.

Concomitantly, an analysis of the inflammatory markers present in the blood during the study was conducted to evaluate whether ASEA Redox plays any role in mitigating or modulating inflammation. For this purpose, Interleukin-1ß (IL-1ß), Interleukin-6 (IL-6), and total glutathione (GSH) were analyzed.

The results showed a decrease in IL-1ß and IL-6 at Days 60 and 120 compared to baseline (Table 2).

All individuals began the study with a consistent IL-1B baseline of 6.5 pg/mL, establishing a uniform foundation for evaluating the supplement's effects. At the 60-day mark, the majority (15 out of 18) showed no change, while a small subset (IDs 21, 24, and 26) exhibited a dramatic reduction, suggesting potential early or delayed responsiveness. By 120 days, the supplement demonstrated a pronounced impact, with 17 out of 18 individuals showing substantial reductions in IL-1B levels, indicating a strong anti-inflammatory effect over time. Interestingly, one individual (ID 5) exhibited stable inflammatory marker levels throughout the study, indicating that the supplement may have contributed to the maintenance of an optimal baseline profile (Figure 1).

Paired t-test comparing baseline to day 120 confirmed a strong and significant reduction ($p<0.0001$) in IL-1ß levels, even though all individuals were already within the ideal range.

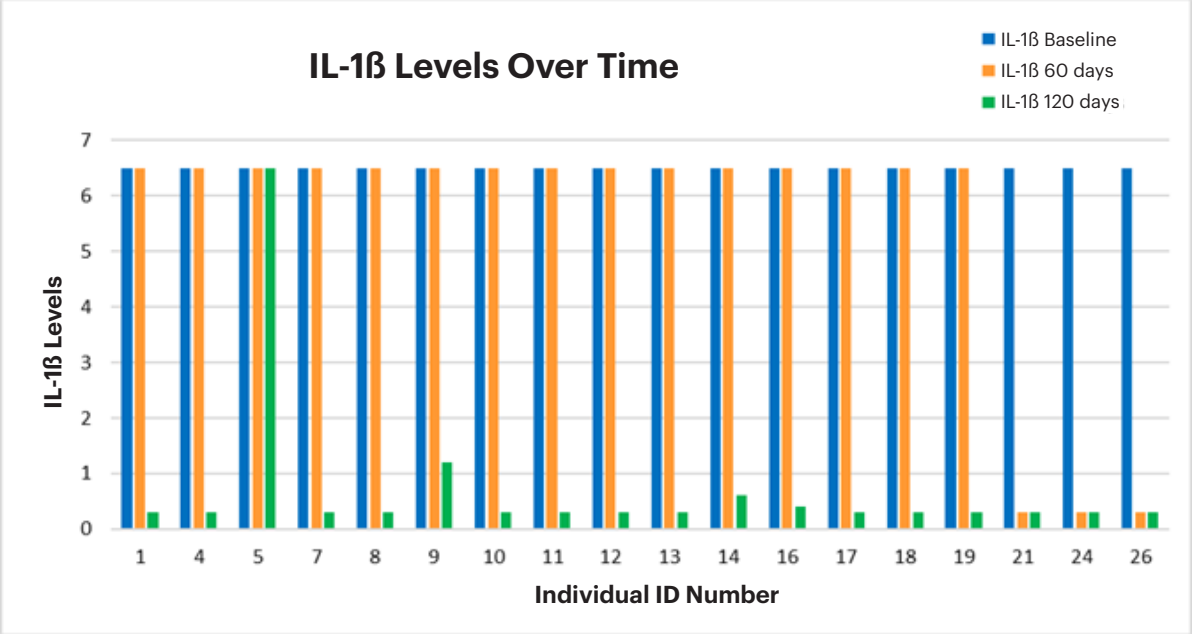

Figure 1: Most individuals (15 out of 18) had no change at 60 days, maintaining IL-1B at baseline levels. Three individuals (IDs 21, 24, 26) showed a dramatic decrease in 60 days. By 120 days, almost all individuals experienced a substantial reduction in IL-1ß levels, with most showing a decrease. Only one individual (ID 5) maintained IL-1B at baseline levels throughout.

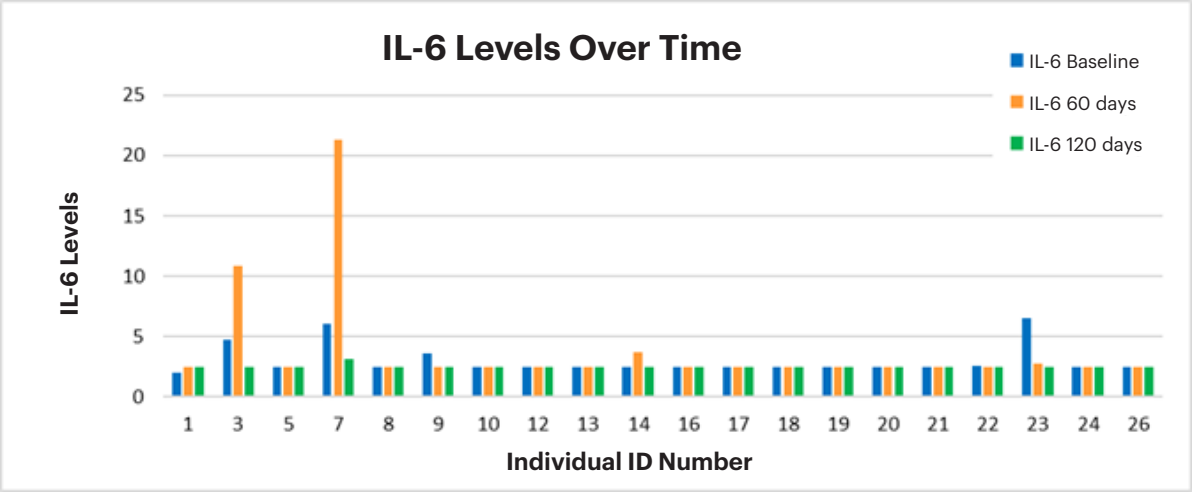

Figure 2: Individual responses at baseline, 60 days, and 120 days indicate minimal variation, suggesting limited supplement impact on this inflammatory marker.

The effect of ARS regimen on GSH levels over time is illustrated in Figure 3. The data reveals a consistent upward trend, with most participants showing increased GSH levels at both the 60-day and 120-day checkpoints compared to baseline.

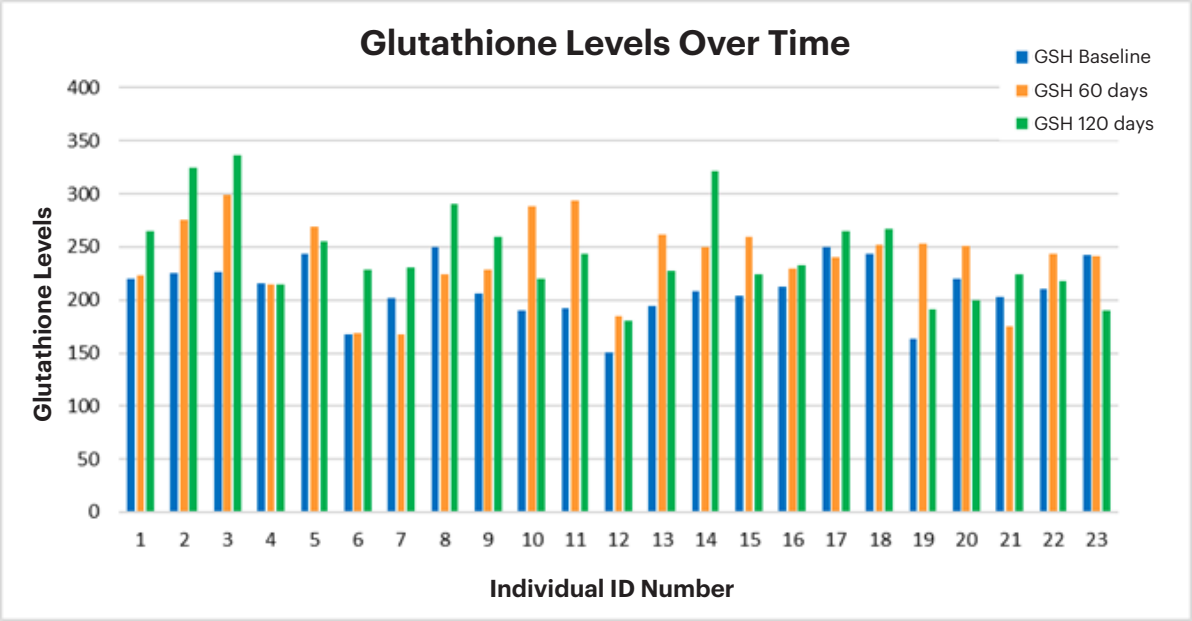

Figure 3: Individual responses at baseline, 60 days, and 120 days show a progressive increase in antioxidant capacity, with an average 10.93% rise by Day 60 and a total 14.43% increase by Day 120, indicating consistent supplement-driven enhancement across most subjects.

Overall, GSH levels increased significantly over the 120-day period, as confirmed by the paired t-test ($p<0.001$). These findings demonstrate a consistent and meaningful enhancement in antioxidant status among participants following the ARS regimen.

Notably, some participants experienced substantial gains by Day 120, whereas a few exhibited only modest improvements or even slight declines. Notably, some participants experienced substantial gains by Day 120, while others showed more modest improvements or slight declines.

DISCUSSION

The 16-week study on ASEA Redox Supplement (ARS) suggested it may promote a coordinated physiological response, particularly in enhancing immune function, antioxidant capacity, and stress resilience. All blood parameters remain within normal reference ranges, indicating the supplement is well-tolerated and does not disrupt key metabolic functions. A consistent increase in Total Glutathione (GSH) by approximately 14.4% was observed, pointing to improved antioxidant protection and cellular defense against oxidative stress—an essential factor in healthy aging and detoxification.

A standout finding was the substantial reduction in Interleukin-1 Beta (IL-1ß), a pro-inflammatory cytokine commonly elevated in chronic inflammation. Most participants experienced up to a 95% decrease, suggesting potent anti-inflammatory properties. Interleukin-6 (IL-6) levels declined by about 11.5%, though with more variability. Stable IL-6 levels in most individuals may reflect maintained immune homeostasis, while declines in those with elevated baselines suggest a positive anti-inflammatory effect. Transient IL-6 spikes in a few participants could be due to temporary immune activation, individual variability, or unrelated physiological events. These time-dependent effects imply that ARS may require sustained use to exert its full biological impact, possibly through gradual immune modulation or accumulation of active compounds.

Further analysis revealed individual differences in biomarker trajectories, with most participants showing strong IL-1ß reductions by day 120, while IL-6 responses varied. GSH levels generally trended upward, reinforcing the supplement's role in enhancing redox balance. Three distinct glutathione response patterns emerged: a majority of individuals (e.g., IDs 1, 2, 3, 5, etc.) showed consistent increases at both time points, supporting the supplement's efficacy; a small subset (IDs 4 and 23) were non-responsive, possibly due to biological resistance or baseline oxidative stress; and others (IDs 7, 8, 17, etc.) exhibited variable responses, likely influenced by lifestyle or physiological fluctuations. The average GSH increases at 120 days were statistically significant ($p < 0.01$), aligning with the observed reductions in IL-1ß and IL-6. The magnitude of IL-1ß suppression suggests that ARS may exert its effects through mechanisms such as NF-κB inhibition, inflammasome modulation, or enhancement of anti-inflammatory cytokines like IL-10. These mechanistic insights, combined with the observed biomarker trends, support the potential of ARS in managing chronic inflammation and aging-related immune dysregulation, commonly referred to as "inflammaging." This triad of effects—antioxidant enhancement, inflammation reduction, and immune regulation—underscores the supplement's promise for promoting long-term physiological resilience and healthy aging.

Taken together, the observed increases in glutathione and reductions in IL-1ß and IL-6 present a compelling, aligned physiological response to supplementation with ASEA Redox. The consistent elevation of glutathione across most individuals reflects enhanced antioxidant capacity and cellular resilience, while the substantial suppression of IL-1ß demonstrates a potent anti-inflammatory effect. IL-6 responses, though more variable, generally trend toward stability or normalization, suggesting the supplement may help maintain immune homeostasis. These outcomes are particularly meaningful in the context of long-term wellness, as they indicate that the supplement not only supports redox balance but also modulates key inflammatory pathways. This triad of effects—antioxidant enhancement, inflammation reduction, and immune regulation—positions the supplement as a promising candidate for managing chronic inflammation, promoting healthy aging, and reinforcing systemic resilience against physiological stressors.

CONCLUSION

Well-Tolerated and Safe

The supplement did not cause any adverse changes in blood parameters. All measured values remained within normal reference ranges, confirming ARS safety at the administered dosage.

Enhanced Antioxidant Capacity

A 14.4% increase in Total Glutathione suggests improved cellular defense against oxidative stress, supporting detoxification and contributing to healthy aging.

Balanced Immune Activity

A nearly 89% reduction in IL-1ß and an 11.5% decrease in IL-6 indicate a more regulated immune response, which may help the body respond more effectively to daily physiological challenges.

Support for Stress Resilience

The combined antioxidant and immune-modulating effects suggest that the supplement may enhance the body's ability to manage environmental and internal stressors.

Overall Wellness Potential

These findings provide a strong foundation for considering ASEA Redox Cell Signaling Supplement as a safe and potentially beneficial option for individuals seeking to support immune function, improve cellular health, and promote overall wellness.

GCP STATEMENT

This study was designed to be performed in full compliance with the protocol, the International Conference on Harmonization Good Clinical Practices (ICH-GCP), and applicable regulatory requirements. All required study documentation was archived as mandated by regulatory authorities.

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