



**Fenestra Research Labs**

*The World Leader In Wellness Studies*

**Human Clinical Trial**

**Preliminary**

Evaluating the Safety and Efficacy of

Product: ***Adya Clarity***

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FINAL REPORT

SUBMITTED TO:

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## **STUDY OUTLINE**

**STUDY TYPE:** Randomized Controlled Clinical Trial

**STUDY DESIGN:** Evaluation, Randomized, Efficacy Study, Fifty Subject Study

**OFFICIAL TITLE:** A 30-Day, Randomized, Preliminary Study

### **1.0 STUDY PURPOSE**

To provide scientific data to evaluate and establish the safety and effectiveness of **Adya Clarity** on removing the high heavy metals levels in the human body.

### **2.0 STUDY OVERVIEW**

#### 2.1 Screening and Testing Procedures

Initial screening of subjects completed before the baseline data was taken for this test included; AST, ALT, to assess liver function, creatinine to help evaluate kidney function, TSH for thyroid assessment, a standard CBC panel was drawn. Each of these tests was run on arterial blood drawn following standardized protocol for the procedures and completed by healthcare professionals.

#### 2.2 Protocol

Following the initial screening at Visit 1 (week 0), subjects who meet all inclusion criteria and none of the exclusion criteria during the intake at Visit 1 were then entered into the study groups.

#### 2.3 Heavy Metal Testing (aluminum, lead, mercury, arsenic)

The above heavy metal blood levels were monitored in each subject for two months prior to this study to establish their consistency in these subjects. Each subject had less than a 200ppm change in these levels for the two months prior to starting this starting. Arterial blood levels were tested using fresh never frozen samples. Standard procedures were followed for all extraction and testing of samples.

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## 2.4 Procedure for blood draws

Our healthcare professional:

- ✓ Wrap an elastic band around the upper arm to stop the flow of blood. This makes the veins below the band larger so it is easier to put a needle into the vein.
- ✓ Clean the needle site with alcohol.
- ✓ Insert the needle into the vein.
- ✓ Attach a tube to the needle to fill it with blood.
- ✓ Remove the band from the subjects arm when enough blood is collected into the vial.
- ✓ Apply a gauze pad or cotton ball over the needle site as the needle is removed.
- ✓ Apply pressure to the site and then a bandage.

## 2.5 Protocol for this Study

1. Each subject was provided clean purified water to be consumed for the duration of this study.
2. Subjects instructions for consuming the test product were as follows:

Using the clean purified water provided to them: **add 5 drops of Adya Clarity per 8 ounces of water being consumed. If one liter containers are to be used then one teaspoon of Adya Clarity should be added directly to each liter before consumption. We recommend they consume 1/2 of their weight in ounces daily of clean water.**

3. No diet changes were to be made.

## 2.6 INCLUSION CRITERIA

- Subjects who signed a written informed consent consistent with required guidelines and meet prior to participation in the trial.
- Subjects 18 years of age or older, either sex.

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- Subjects who have aluminum levels of at least 250ppm for the 2 months prior to this study and on the first day of this study.
- Subjects who have lead levels of at least 200ppm for the 2 months prior to this study and on the first day of this study.
- Subjects who have mercury levels of at least 250ppm for the 2 months prior to this study and on the first day of this study.
- Subjects who have arsenic levels of at least 200ppm for the 2 months prior to this study and on the first day of this study.
- Subjects who are not on any medication or dietary supplement.
- Subjects who have normal kidney, liver, and thyroid functions, normal CBC prior to the start date of this study.
- Subjects who are able to follow the protocol as designed by and Fenestra Research Labs
- In generally good health.

## 2.7 EXCLUSION CRITERIA

- History of head trauma
- History of serious diseases or illness diagnosed at this time.
- Known moderate to severe renal insufficiency.
- Recent history (<6 months prior to Visit 1) of myocardial infarction.
- Subjects who regularly use oxygen therapy.
- Subjects with known active tuberculosis.
- Subjects with a history of cancer within the last 5 years.
- Subjects with treated basal cell carcinoma are allowed.

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- Subjects who have undergone thoracotomy with pulmonary resection within 1 year prior to the trial.
- Subjects who are currently in a pulmonary rehabilitation program or who have completed a pulmonary rehabilitation program in the 6 weeks prior to the screening visit (Visit 1).
- Subjects currently prescribed diuretic medications, cardiac stimulants, or any other prescribed or non-prescribed medication that may, in the opinion of the Fenestra Research staff, alter testing results.
- Use of opiate analgesics prescribed or otherwise obtained for any treatment reason including migraine treatment, or for recreation.
- History of drug or alcohol addiction in the last 5 years.
- Females who are pregnant, lactating, or nursing or who may become pregnant during the course of the study.
- Patients diagnosed as HIV-positive, diagnosed with AIDS, or with any neuromuscular condition including CP, MS, ALS, or Huntington's Chorea
- Patients with uncontrolled hypertension (*e.g.* BP>150/100).
- Subjects who have used steroid therapy with-in the last 6-months.
- Patients with any condition not previously named that, in the opinion of the investigators or intake staff, would jeopardize the safety of the patient or affect the validity of the data collected in this study.

## 2.0 Study Design

Subjects were instructed to change nothing in their lives except the water they drank. No dietary or exercise changes were to be made. No other supplements or medications were to be used. Subjects were monitored with by-weekly phone calls from Fenestra Research Labs staff member.

## 3.0 CLINICAL DATA ANALYSIS

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#### 4.1 General Information

Mean Age: 43 ± 4 yrs

Males-23

Females- 27

#### **4.0 CONCLUSION**

Based on these preliminary clinical comparisons and data this product was shown to be a safe and effective for short term human use. There were No reports of allergies, reactions, or interaction with any other product for the duration of this study by any of the subjects.

For the duration of this study the amounts of heavy metals reduced in this study are impressive.

Aluminum levels were reduced from day one of this study to day thirty by an average of 42%.

Lead level were reduced from day one of this study to day thirty of this study by an overall average of 40%

Mercury levels were reduced from day one of this study to day thirty by an average of 42%.

Arsenic levels were reduced from day one of this study to day thirty of this study by an overall average of 45%.

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