

Safety and Effectiveness Study
Human Clinical Study
125 Subjects Over 30 Days
2022

Manufacturer: LongStar Health Pro Incorporated
Product: InnerPure®

Clinical Study run by and reported on by:

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Overview

InnerPure® is an all-natural herbal supplement that has been extracted and processed to release toxins from the body.

All ingredients are vegan and were produced using no GMOs. This supplement is cGMP-certified and tested in an independent, third-party laboratory.

Study Product Ingredients

Proprietary blend 400 mg *

Rhubarb extract

Atractylodes extract

Aurantii fructus immaturus

Lotus leaf powder

Rubia yunnanesis

Cynanchum otophyllum

Cistanche powder

Ginseng extract

Other ingredients: gelatin, glycerin, purified water.

Study Overview

This Safety and Effectiveness Study was conducted to evaluate the effects on the human body, organs, and systems with the ingestion of InnerPure® supplement over thirty (30) days.

It was the objective to make this study broad as to provide a comprehensive understanding of this product.

Inclusion Criteria

- Eighteen to seventy (18 – 70) years of age on day one (1) of this study
- Men and women

Exclusion Criteria

- Dangerously high blood pressure above 180/90
- Fragile blood-sugar levels
- Surgery within the past six (6) months
- Cancer diagnosis within the past five (5) years
- Alcohol abuse within the past five (5) years
- Drug abuse within the past five (5) years
- Inability to walk and or move about

- Inability to follow the protocol of this study
- Inability to follow directions given by staff
- Serious head injury within the past five (5) years
- Pregnant or nursing
- History of head trauma
- Marijuana use in the past three (3) months
- Issues with daily bowel movements
- Tested positive for Covid within the past three (3) months
- Head trauma within the past five (5) years

Mean age = 46 ± 5 years old

Male: Female: 62:63

P value overall = 0.03

Areas of Evaluation Pre-Study

Before admittance to this study, each subject had arterial blood drawn to establish their organs' and systems' health.

Vitals signs were taken.

Weight was taken.

Consent to study participation was signed.

History and health intake questions were answered.

Protocol

This study was made up of one-hundred and twenty-five (125) subjects. With one hundred (100) subjects taking InnerPure®. Specifically, thirty-four (34) subjects took one (1) capsule twice daily, thirty-three (33) subjects took two (2) capsules twice daily, and thirty-three (33) subjects took three (3) capsules twice daily for the thirty (30) days of this study.

The twenty-five (25) subjects on placebo took one (1) capsule twice daily for the thirty (30) days of this study.

Day 0

Possible subjects were evaluated for this specific study. Arterial blood draws to collect blood samples were collected. Oral intake and histories were taken. All other possible information was collected and evaluated for participation of this study.

Arterial-blood testing that was run included:

Alanine transaminase (ALT): an enzyme that primarily exists in the liver. An ALT blood test is usually included in a liver panel and comprehensive metabolic panel, and healthcare providers use it to help assess the liver health.

Aspartate transferase (AST): an enzyme that is found in the liver, heart, pancreas, muscles, and other tissues in body. An AST blood test is often included in a liver panel and comprehensive metabolic panel, and healthcare providers most often use it to help assess the liver health.

Alkaline phosphatase (ALP): an enzyme found throughout the body. ALP blood tests measure the level of ALP in the blood that comes from the liver and bones, and it is one of the tests included in a comprehensive metabolic panel. High levels of ALP in the blood may indicate liver disease or certain bone disorders.

Complete blood count (CBC): a blood test used to help evaluate overall health and detect a wide range of disorders, including anemia, infection, and leukemia.

A complete blood count test measures several components and features of blood, including:

- Red blood cells, which carry oxygen
- White blood cells, which fight infection
- Hemoglobin, the oxygen-carrying protein in red blood cells
- Platelets, which help with blood clotting
- Blood urea nitrogen (BUN) test reveals important information about how well the kidneys are working. A BUN test measures the amount of urea nitrogen that's in the blood.

Here's how the body typically forms and gets rid of urea nitrogen:

The liver produces ammonia — which contains nitrogen — after it breaks down proteins used by your body's cells.

The nitrogen combines with other elements, such as carbon, hydrogen and oxygen, to form urea, which is a chemical waste product.

The urea travels from the liver to the kidneys through the bloodstream.

Healthy kidneys filter urea and remove other waste products from the blood.

The filtered waste products leave the body through urine.

A BUN test can reveal whether urea nitrogen levels are higher than normal, suggesting that the kidneys may not be working properly.

Safety of the Product

In order to assess if a product, natural or not, is having negative effects on the body these cellular indicators must be evaluated before and after use of the product.

Day 1

All chosen subjects were randomly placed into groups. Groups consisted of:

- Thirty-four (34) subjects taking one (1) capsule twice daily of InnerPure
- Thirty-three (33) subjects taking two (2) capsules twice daily of InnerPure
- Thirty-three (33) subjects taking three (3) capsules twice daily of InnerPure
- Twenty-five (25) subjects taking a placebo product one (1) capsule twice daily

This study followed double-blind procedures. All subjects and staff members were kept blind to the knowledge of if the subject was taking the live product or the placebo product. This study was also a placebo-controlled study.

All subjects signed an Informed Consent to enter this study.

All subjects were given a group information talk as well as a one-on-one meeting to go over the protocol and all other details of this study.

Subjects were informed NOT to change any of their daily habits including eating, drinking, exercise, or sleep for this study. If changes came naturally that was acceptable.

All subjects were told to take the product in the morning hours with food and again in the evening with food.

All subjects were informed that if they missed taking the product to take it that day as soon as they remembered.

All subjects were provided a 24-hour number where they could reach a health-care professional if they needed.

All subjects were informed to tell all EMT's, doctors, or health-care providers they worked with that they were participating in a human clinical study and taking a test product.

All subjects were contacted bi-weekly by phone to ensure compliance.

Testing

Day 1

Blood was drawn from arterial veins of each subject following standard laboratory procedures.

For each sample that was collected three (3) separate tubes were collected. The stated number for each data point is the average of the three (3) separate vial's test data.

Subjective intakes were given to each subject and collected. This was completed on a smart tablet used for only this purpose.

Questionnaires were completed on smart tablets.

Day 15

Subjects were brought back to the health-care professionals' offices to evaluate their compliance, weight, and have all laboratory blood tests performed.

Day 30

Arterial blood draws were taken.

Subjective intakes were given to each subject and collected. This was completed on a smart tablet used for only this purpose.

Questionnaires were completed on smart tablets.

Testing Blood Urea Nitrogen (BUN)

Bilirubin is a yellow compound that occurs in the normal catabolic pathway that breaks down heme in vertebrates. This catabolism is a necessary process in the body's clearance of waste products that arise from the destruction of aged or abnormal red blood cells. First the hemoglobin gets stripped of the heme molecule which thereafter passes through various processes of porphyrin catabolism, depending on the part of the body in which the breakdown occurs. For example, the molecules excreted in the urine differ from those in the feces. The production of biliverdin from heme is the first major step in the catabolic pathway, after which the enzyme biliverdin reductase performs the second step, producing bilirubin from biliverdin.

A bilirubin test measures the amount of bilirubin in the blood. It's used to evaluate the cause of health concerns like jaundice, anemia, and liver disease.

If bilirubin levels are higher than normal, it is an indicator that either red blood cells are breaking down at an unusual rate or that the liver is not breaking down waste properly and clearing the bilirubin from the blood.

A UNISTAT bilirubinmeter was used.

Negative- normal

Live-Product Group Test Results

Day 1

All one hundred (100) subjects were Negative

Day 15

All one hundred (100) subjects were Negative

Day-30

All one hundred (100) subjects were Negative

Placebo Group

Day-1

All twenty-five (25) subjects were Negative

Day-15

All twenty-five (25) subjects were Negative

Day-30

All twenty-five (25) subjects were Negative

Albumin

Albumin is a protein that is produced in the liver. Albumin enters the bloodstream where it helps carry vitamins, enzymes, and other important substances. Albumin also helps prevent fluids from leaking out of the bloodstream.

An albumin blood test measures the amount of albumin in a sample of blood. It can be used to help identify various health conditions, including problems that affect the liver and kidney.

The test measures the total amount of the albumin in the blood. Albumin is a protein that is produced in the liver and then enters the bloodstream where it is carried to other parts of the body. Albumin's biological functions are to keep fluid from leaking out of the blood and to carry substances like hormones, enzymes, and vitamins in the body.

A nitrogen-albumin human ELISA kit was used.

3.4-5.4 g/dL is normal.

Live-Product Group Test Results

Day- 1

3.7g/dL was the group average

Day-15

4.2g/dL was the group average

Day 30

4.2g/dL was the group average

Placebo Group Test Results

Day-1

4.8g/dL was the group average

Day-15

4.1gdL was the group average

Day-30

3.9g/dL was the group average

Color of Urine

Normal urine color ranges from pale yellow to deep amber, the result of a pigment called urochrome and how diluted or concentrated the urine is.

Pigments and other compounds in certain foods and medications can change urine color. Beets, berries, and fava beans are among the foods most likely to affect the color. Many over-the-counter and prescription medications give urine vivid tones, such as red, yellow, or greenish blue.

Appearance of Urine

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Clear-yellow is normal.

Live-Product Group Test Results

Day 1

All one hundred (100) subjects had clear-yellow color urine

Day 15

All one hundred (100) subjects had clear-yellow color urine

Day 30

All one hundred (100) subjects had clear-yellow urine

Placebo Group Test Results

Day 1

All twenty-five (25) subjects had clear-yellow color urine

Day 15

All twenty-five (25) subjects had clear-yellow color urine

Day 30

All twenty-five (25) subjects had clear-yellow urine

Urine pH

The pH scale is used to measure the acid and alkaline present in various fluids. The pH scale ranges from 0 to 14. A pH of 7 is neutral, whereas a pH result below 7 is acidic and above 7 is alkaline.

Urine has the highest range of pH compared to other bodily fluids. The American Association for Clinical Chemistry says the normal urine pH range is between 4.5 and 8. Any pH higher than 8 is basic or alkaline, and any under 6 is acidic.

5 - 8 pH is normal.

Live Product Group Test Results

Day 1

Group average: 6.4pH

Day 15

Group average: 6.5pH

Day 30

Group average: 6.9pH

Placebo Group Test Results

Day 1

Group average: 6.7pH

Day 15

Group average: 6.6pH

Day 30

Group average: 6.5pH

Specific Gravity

Specific gravity is the ratio of the density of a substance to the density of a reference substance. Apparent specific gravity is the ratio of the weight of a volume of the substance to the weight of an equal volume of the reference substance. The reference substance is nearly always water at its densest, for liquids and for gases, air at room temperature. That being stated, temperature and pressure must be specified for both the sample and the reference. Pressure is nearly always 1 atm equal to 101.325 kPa. Temperatures for both sample and reference vary from industry to industry. Specific gravity is commonly used in industry as a simple means of obtaining information about the concentration of solutions of various materials such as brines, hydrocarbons, sugar solutions and acids.

A urine concentration test provides the specific gravity of urine. This measures the kidneys' ability to balance water content and excrete waste. It is important in diagnosing some health conditions that impact water content in the urine.

The formula for Specific Gravity:

Specific Gravity = Density of object divided by Density of water

1.005-1.028Kg/m³ is normal.

Live Product Group Test Results

Day 1

Group average: 1.014Kg/m³

Day 15

Group average: 1.013Kg/m³

Day 30

Group average: 1.016Kg/m³

Placebo Group Test Results

Day 1

Group average: 1.013Kg/m³

Day 15

Group average: 1.014Kg/m³

Day 30

Group average: 1.013Kg/m³

Glucose

Glycosuria, or glucose in the urine, is the presence of higher than normal levels of sugar in the urine and may be due to complications with the kidneys or diabetes.

Test Result	MG/DL	MMOL/L	Meaning
Glucose in urine: Trace	100mg/dL	5.55	There is a slight presence of glucose in the urine, meaning blood sugar is high.
Glucose 1+	250mg/dL	11.1	250mg/dL of glucose is being lost via urine
Glucose 2+	500mg/dL	27.75	500mg/dL is being lost via urine
Glucose 3+	1000mg/dL	55.5	More than 1000mg/dL of blood sugar is being lost through urine
Glucose 4+	2000mg/dL	111	Over 2000mg/dL of blood glucose is being lost through urine

Negative is normal.

Live Product Group Test Results

Day-1

All one hundred (100) subjects: Negative

Day-15

All one hundred (100) subjects: Negative

Day-30

All one hundred (100) subjects: Negative

Placebo Group Test Results

Day-1

All twenty-five (25) subjects: Negative

Day 15

All twenty-five (25) subjects: Negative

Day 30

All twenty-five (25) subjects: Negative

Ketone

A ketone in urine test measures ketone levels in urine. Normally, the cells in the body use glucose (sugar) from the blood for energy. If the cells can't get enough glucose, the body breaks down fat for energy instead. This produces an acid called ketones, which can build up in the blood and urine.

Having some ketones in urine is normal. But high ketone levels in urine may be a sign that the body is too acidic. This condition is called ketoacidosis. The most common type of ketoacidosis is a complication of diabetes called diabetic ketoacidosis (DKA). Diabetic ketoacidosis is a medical emergency that often develops quickly and can even be life-threatening.

Negative is normal.

Live Product Group Test Results

Day 1

All one hundred (100) subjects: Negative

Day 15

All one hundred (100) subjects: Negative

Day 30

All one hundred (100) subjects: Negative

Placebo Group Test Results

Day 1

All twenty-five (25) subjects: Negative

Day 15

All twenty-five (25) subjects: Negative

Day 30

All twenty-five (25) subjects: Negative

Urobilin

A urobilinogen in urine test measures the amount of urobilinogen in a urine (pee) sample. Normal urine contains some urobilinogen. Too much urobilinogen in urine may be a sign of a liver disease, such as hepatitis or cirrhosis, or certain types of anemia. Little or no urobilinogen may be a sign of other problems with the liver, gallbladder, or bile ducts.

Urobilinogen comes from bilirubin. The body makes bilirubin during the normal process of breaking down old red blood cells. The liver uses the bilirubin to make bile, a fluid that helps to digest food in the

intestines. Some bile flows through ducts (small tubes) from the liver directly into the intestines. The rest is stored in the gallbladder for when it is needed.

Good bacteria in the intestines breaks down the bilirubin in bile and makes urobilinogen. Some of the urobilinogen leaves the body in stools (poop). Some of it enters the bloodstream and returns to the liver, where it is "recycled" into bile. A small amount of urobilinogen leaves the body in urine.

Little or no urobilinogen in urine may mean that something is blocking bile from flowing into the intestines. High levels of urobilinogen in urine may be a sign that:

- The liver is making too much bilirubin because the body breaks down red blood cells faster than it can make them. This condition is called hemolytic anemia.
- The liver can't recycle urobilinogen into bile because of liver disease.

<2.0mg/dL is normal.

Live Product Group Test Results

Day 1

Group average: 0.98mg/dL

Day 15

Group average: 0.96mg/dL

Day 30

Group average: 1.02mg/dL

Placebo Product Group Test Results

Day 1

Group average: 1.06mg/dL

Day 15

Group average: 1.01mg/dL

Day 30

Group average: 1.1mg/dL

Nitrates

The presence of nitrates in urine is often considered a predictor of a urinary tract infection (UTI). Development of urinary tract infections are more commonly experienced by women, owing to their shorter urethra length compared to men. This allows for bacteria to have an easier time reaching and infecting the urinary tract system. A UTI can potentially lead to inflammation and irritation in the lining of the urethra, kidneys, and ureters, leading to much patient discomfort.

Negative is normal.

Live Product Group Test Results

Day 1

All one hundred (100) subjects: Negative

Day 15

All one hundred (100) subjects: Negative

Day 30

All one hundred (100) subjects: Negative

Placebo Group Test Results

Day 1

All twenty-five (25) subjects: Negative

Day 15

All twenty-five (25) subjects: Negative

Day 30

All twenty-five (25) subjects: Negative

Leukocytes

Leukocytes are white blood cells that help the body fight germs. When there are more of these than usual in the urine, it's often a sign of a problem somewhere in the urinary tract.

A common reason for leukocytes in urine and other symptoms include a urinary tract infection (UTI).

The urinary tract includes the kidneys, bladder, and ureters (tubes that carry urine from the kidneys to the bladder). An infection in the urinary tract is the most likely cause of leukocytes in the urine. Any time there is an infection, the immune system ramps up production of these cells to fight off the bacteria.

Negative is normal.

Live Product Group Test Results

Day 1

All one hundred (100) subjects: Negative

Day 15

All one hundred (100) subjects: Negative

Day 30

All one hundred (100) subjects: Negative

Placebo Group Test Results

Day 1

All twenty-five (25) subjects: Negative

Day 15

All twenty-five (25) subjects: Negative

Day 30

All twenty-five (25) subjects: Negative

RBC

Red blood cells (RBC) can be present in urine even when not visible to the unaided human eye. The medical term for RBC in the urine is hematuria.

There are two types of hematuria. One is called “gross hematuria,” which occurs when a person can see the blood in their urine. The other type is “microscopic hematuria,” wherein a person cannot see the blood in their urine, even though RBC are present.

However, RBC in the urine is usually a symptom of an underlying health condition. A doctor will typically test for RBC content during a urine test. They will then use the results to help determine what the next course of action should be.

0-5HPF is normal.

Live Product Group Test Results

Day 1

Group average: 3.02HPF

Day 15

Group average: 2.84HPF

Day 30

Group average: 3.13HPF

Placebo Group Test Results

Day 1

Group average: 2.84HPF

Day 15

Group average: 2.72HPF

Day 30

Group average: 2.84HPF

WBC

White blood cells are a part of the immune system protecting the body from infection. These cells circulate through the bloodstream and tissues to respond to injury or illness by attacking any unknown organisms that enter your body. As white blood cells travel through the bloodstream and tissues, they locate the site of an infection and act as an army general to notify other white blood cells of their location to help defend the body from an attack of an unknown organism. Once the white blood cell legion arrives, they fight the attacker by producing antibody proteins to attach to the organism and destroy it. White blood cell formation occurs in the soft tissue inside of your bones (bone marrow). Two types of white blood cells (lymphocytes) grow in the thymus gland (T cells) and lymph nodes and spleen (B cells).

0-3HPF is normal.

Live Product Group Test Results

Day 1

Group average: 1.86HPF

Day 15

Group average: 1.82HPF

Day 30

Group average: 2.02HPF

Placebo Group Test Results

Day 1

Group average: 1.8HPF

Day 15

Group average: 1.88HPF

Day 30

Group average: 1.8HPF

AST

Aminotransferase (AST) is an enzyme that is present in a variety of tissue. An enzyme is a protein that helps trigger chemical reactions.

AST is found in the highest concentrations in the liver, muscles, heart, kidney, brain, and red blood cells. A small amount of AST is typically in the bloodstream. Higher-than-normal amounts of this enzyme in the blood may be an indication of a health problem. Above normal levels may be associated with liver injury.

AST levels increase when there is damage to the tissues and cells where the enzyme is found.

The AST test measures the amount of AST in the blood that has been released from injured tissue. An older name for the test is serum glutamic-oxaloacetic transaminase (SGOT).

AST test is used to check for liver conditions, such as hepatitis. It is usually measured together with alanine aminotransferase (ALT). According to liver specialists, abnormal ALT results are more likely related to liver injury than abnormal AST results.

Checkmarx was used for testing.

5-40 IU/L is normal.

Live Product Group Test Results

Day 1

Group average: 22.76 IU/L

Day 15

Group average: 22.78 IU/L

Day 30

Group average: 22.85IU/L

Placebo Group Test Results

Day 1

Group average: 22.64IU/L

Day 15

Group average: 22.76IU/L

Day 30

Group average: 24.4IU/L

ALT

Alanine transaminase (ALT) is a transaminase enzyme. It is also called alanine aminotransferase and was formerly called serum glutamate-pyruvate transaminase or serum glutamic-pyruvic transaminase. ALT was first characterized in the mid-1950s by Arthur Karmen and colleagues. ALT is found in plasma and in various body tissues but is most common in the liver. It catalyzes the two parts of the alanine cycle. Serum ALT level, serum AST level, and their ratio are commonly measured clinically as biomarkers for liver health.

ALT is normally found inside liver cells. However, when the liver is damaged or inflamed, ALT can be released into the bloodstream. This causes serum ALT levels to rise. Many times, an increase in ALT is the first sign of a problem and is elevated before other symptoms start to appear.

Alanine Aminotransferase (SGPT Test) was used.

7-55 IU/L is normal.

Live Product Group Test Results

Day 1

Group average: 28.14 IU/L

Day 15

Group average: 27.85IU/L

Day 30

Group average: 28.56IU/L

Placebo Group Test Results

Day 1

Group average: 30.88IU/L

Day 15

Group average: 31.8IU/L

Day 30

Group average: 29.2IU/L

APL

The alkaline phosphatase test (ALP) is used to help detect liver disease or bone disorders. In conditions affecting the liver, damaged liver cells release increased amounts of ALP into the blood. This test is often used to detect blocked bile ducts because ALP is especially high in the edges of cells that join to form bile ducts.

Alkaline phosphatase is one kind enzyme found in the body. Enzymes are proteins that help chemical reactions happen.

There are alkaline phosphatase throughout the body, including the liver, digestive system, kidneys, and bones.

APL requires cytogenetic analysis, or the evaluation of chromosomes. Cytogenetic analysis can be done with several testing methods, including karyotyping, fluorescent in situ hybridization (FISH), immunostaining, and reverse transcription–polymerase chain reaction (RT-PCR).

44-147 IU/L is normal.

Live Product Group Test Results

Day 1

Group average: 106IU/L

Day 15

Group average: 102IU/L

Day 30

Group average: 102IU/L

Placebo Group Test Results

Day 1

Group average: 86

Day 15

Group average: 87

Day 30

Group average: 87

Weight

Maintaining a healthy body weight is imperative to staying healthy. As people gain weight, their risks for high blood pressure, diabetes, high blood cholesterol, and heart disease all increase.

For adults, preventing weight gain as the body ages is critical, no matter the current body weight. People who are overweight or obese may need to lose weight to improve their health.

As a normal weight for someone has many varying factors, we cannot make a statement for each subject nor a group of subjects as to what or how much they should weigh. So, we will simply state the average weight of each group at each testing point of this study.

A SECA 710 Balance Beam Scale was used.

A balance beam scale with waste level tiders was used to measure each subjects correct weight.

Each subject was weighed in standard U.S. pounds.

Live Product Group 1

Day 1

Average weight: 163.5 lbs.

Day 15

Average weight: 162.7 lbs.

Day 30

Average weight: 158.4 lbs.

Live Product Group 2

Day 1

Average weight: 171.2 lbs.

Day 15

Average weight: 169.9 lbs.

Day 30

Average weight: 166.9 lbs.

Live Product Group 3

Day 1

Average weight: 170.7 lbs.

Day 15

Average weight: 168.7 lbs.

Day 30

Average weight: 166.4 lbs.

Placebo Group

Day 1

Average weight: 171.2 lbs.

Day 15

Average weight: 171.4 lbs.

Day 30

Average weight: 171.4 lbs.

WBC

White blood cells, also called leukocytes or leucocytes, are the cells of the immune system that are involved in protecting the body against both infectious disease and foreign invaders. All white blood cells are produced and derived from multipotent cells in the bone marrow known as hematopoietic stem cells. Leukocytes are found throughout the body, including the blood and lymphatic system.

White blood cells consist of granulocytes (neutrophils, eosinophils, and basophils), monocytes, and lymphocytes.

Leukocytes originate from the bone marrow and consist of granulocytic and mononuclear cells. These cells are important in both the innate and adaptive immune response. Characterization of increases and decreases of specific cells (neutrophils, eosinophils, basophils, lymphocytes, and monocytes) can help characterize how a subject is responding to a particular antigenic stimulus.

Causes of abnormally high levels or leukocytosis depend on which cell type is increased. An increase in neutrophils or neutrophilia may indicate a stress or inflammatory response. If there is an eosinophilia, parasitemia or a hypersensitivity response should be considered. Lymphocytosis can occur with immune stimulation or associated with epinephrine release which can accompany excitement or exercise.

A decrease in white blood cell numbers or leukopenia can occur with increased tissue demand as can be seen in severe inflammatory responses, endotoxemia, or bone marrow suppression.

Microscopy was used to measure and evaluate levels.

4,500-11,000 microliters (mCL) is normal.

Live Product Group Test Results

Day-1

Average: 7,600 mCL

Day-15

Average: 7,860 mCL

Day-30

Average: 7,246 mCL

Placebo Group Test Results

Day-1

Average: 7,688 mCL

Day-15

Average: 7,944 mCL

Day-30

Average: 7,660 mCL

PLT

Platelets, also called thrombocytes, are a component of blood whose function (along with the coagulation factors) is to react to bleeding from blood vessel injury by clumping, thereby initiating a blood clot. Platelets have no cell nucleus; they are fragments of cytoplasm that are derived from the megakaryocytes of the bone marrow, which then enter the circulation. Circulating inactivated platelets are biconvex discoid structures. Activated platelets have cell membrane projections covering their surface. Platelets are found only in mammals, whereas in other vertebrates, thrombocytes circulate as intact mononuclear cells.

Platelets, the smallest of our blood cells, can only be seen under a microscope. They are shaped like small plates in their non-active form. A blood vessel will send out a signal when it becomes damaged. When platelets receive that signal, they will respond by traveling to the area and transforming into their "active" formation. To make contact with the broken blood vessel, platelets grow long tentacles and then resemble a spider or an octopus.

Too many platelets, too few platelets, abnormally functioning platelets, and related conditions such as blood clots, strokes, and heart attacks can be inherited.

Cellometer X2 was used for PLT.

150,000-450,000 microliters (mCL) is normal.

Live Product Group Test Results

Day-1

Average: 274,150 mCL

Day-15

Average: 271,540 mCL

Day-30

Average: 258,220 mCL

Placebo Group Test Results

Day-1

Average: 231,200 mCL

Day-15

Average: 238,040 mCL

Day-30

Average: 236,640 mCL

Study Details

Day 0

All chosen subjects were screened using blood panels: CBC, and liver enzymes. Urine tests including urinalysis, BUN, and pregnancy testing.

Subjects that meet all the inclusion and none of the exclusion criteria were randomly placed into either the live product group or the control placebo group.

Day 1

One hundred and twenty-five (125) subjects were in this study. Informed consents were signed by each subject individually. Randomized controlled trials (RCT) are known as the best method to prove causality despite various limitations. Random allocation is a technique that chooses individuals for treatment groups and control groups entirely by chance with no regard to the will of researchers or patients' condition and preference. This allows researchers to control all known and unknown factors that may affect results in treatment groups and control groups.

Allocation concealment is a technique used to prevent selection bias by concealing the allocation sequence from those assigning participants to intervention groups, until the moment of assignment.

Allocation concealment prevents researchers from influencing which participants are assigned to a given intervention group. This process must be included in the experiment for the success of any RCT.

Blinding refers to keeping trial participants, health care providers, assessors, or data collectors unaware of the assigned intervention, so that they will not be influenced by that knowledge. This process is conducted to minimize possible bias in implementation, dropouts, measurements, etc. Blinding is not always feasible for RCT but should be implemented if possible.

Randomization, allocation concealment and blinding should be well implemented and should be described in the paper.

Group and one-on-one instructions for taking the test product were given to each subject. A 24-hour emergency healthcare phone number was provided to each subject. Study product was provided, or placebo product was provided to each subject. Subjects were instructed not to change their daily routine, exercise, food intake nor fluid intake for the duration of this study. Subjects were instructed if they felt like increasing their exercise or amounts of healthy foods that was expectable for the duration of this study.

Subjects were supplied product and instructed to take their product based on the group they were in.

As you can see the average weight loss for the subjects in Group #1 was 5.1 pounds. Weight loss for Group #2 was 4.3 pounds. Weight loss for Group #3 was 4.3 pounds. This is a significant amount of weight loss considering the subjects made no changes to their food consumption or exercise.

Questionnaire	Day 1					Day 2				
	No	Sometimes	Often	Usually	Yes	No	Sometimes	Often	Usually	Yes
Do you feel good about your weight?	97	4	10	14	4	96		10	14	4
Do you weigh your food?	##					##				
Do you normally eat breakfast?	23	20	0	68	14	26	20	7	65	7
Do you normally eat lunch?	0	0	2	5	##	0	0	2	13	110
Do you normally eat dinner?	2	2	11	15	95	2	27	11	10	75
Do you snack?	0	21	44	28	32	0	21	32	26	46
Do you exercise?	10	17	20	29	49	10	17	20	29	49
How is your energy level?	51	7	23	9	35	28	9	44	8	36
Are you happy?	0	33	30	23	39	0	33	31	22	39
Do you feel depressed often?	76	5	17	27	0	77	16	32	0	0
Do you seek mental health assistance?	77	7	0	0	41	77	7	0	0	41
How much water do you drink daily?	1- quart-64	1.5 quarts-30	30-I don't know		1- quart-55	I don't know-33				
Do you take daily vitamins?	2	1	21	11	91	We had them stop for this study.				
Do you take daily minerals?	56	6	28	25	10	We had them stop for this study.				
Do you have daily bowel movements?	51	12	37	9	16	0	5	7	14	99

The questionnaire indicates that the number of subjects having NO daily bowel movements was significantly changed from fifty-one (51) subjects on Day 1 to zero (0) subjects on Day 30.

Regular daily bowel movement prevent many health problems such as colon cancer, hypertension, constipation, and more.

Common Causes of Constipation

- Insufficient quantities of fiber and water in meals
- Changes in diet or normal activities
- Physical inactivity
- Holding stool for long periods even with the urge
- Drugs such as narcotics, antidepressants, and anti-acids (especially those rich in Ca and Al)

Constipation Help

- Increasing clean water
- Increasing exercise
- InnerPure® (as shown in this study)

Conclusions

InnerPure® was shown to be safe and effective during this study. There was no negative impact on any organs or systems measured during the course of this study.

No interactions, sensitivities, or side effects were observed or reported during the course of this study. The product was tolerated well by all subjects.

The most significant positive impacts were seen in relieving constipation and weight loss. Subjects on InnerPure® lost an average of four to five (4-5) pounds in thirty (30) days during this study. With constipation we found 100% of subjects had a positive impact when taking InnerPure®. All of the subjects had positive and healthy improvements in their daily bowel movement during this study.

It is my recommendation that further studies continue for a deeper understanding of InnerPure® abilities to improve natural weight loss. A longer study meaning three to six (3-6) months would provide a longer-range analysis of weight loss and the positive benefits it can provide. A longer look at constipation and issues with daily bowel movement would provide data on the long-term benefits InnerPure® can provide with healthy bowel movements and toxin release in the body.

Areas I feel should be looked at in a three to six (3–6) month study are specific toxins, weight loss in different groups (age), adding exercise plans, and tracking inflammatory markers.