



Fenestra Research Labs

The World Leader In Wellness Studies

Human Clinical Trial

PHASE 1

Evaluating the Safety and Efficacy of Product:

CCWS™

(Candida Cell Wall Suppressor)

Distributor: **Candida Labs Co., Ltd.**

FINAL REPORT

Winter 2014

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OVERVIEW

Candida is the scientific name for yeast. It has been estimated that 85% of Americans have, or have had, a candida yeast infection. Health issues that have been associated with candida albican overgrowth include:

- ✓ Sexual Dysfunction
- ✓ Depression
- ✓ Arthritis
- ✓ Chronic Hives,
- ✓ Fatigue
- ✓ Irritability
- ✓ PMS
- ✓ Digestive Disorders
- ✓ Muscle Pain
- ✓ Headaches
- ✓ Memory Loss
- ✓ Vaginitis
- ✓ Skin Problems
- ✓ Hyperactivity
- ✓ Menstrual Problems
- ✓ Urinary Disorders
- ✓ Respiratory Problems
- ✓ Food & Environmental Allergies

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- ✓ Autism
- ✓ Learning Difficulties.

The Center for Disease Control and Prevention has this to say about Candidiasis:

"Candidiasis is a fungal infection caused by yeasts that belong to the genus Candida. There are over 20 species of Candida yeasts that can cause infection in humans, the most common of which is Candidiasis. Candidiasis normally live on the skin and mucous membranes without causing infection; however, overgrowth of these organisms can cause symptoms to develop. Symptoms of candidiasis vary depending on the area of the body that is infected."

STUDY OUTLINE

STUDY TYPE: Randomized, Placebo-Controlled Clinical Trial

STUDY DESIGN: Evaluation, Randomized, Efficacy Study, And Two Hundred-Subject Studies

OFFICIAL TITLE: A 45-Day, Randomized, Phase 1 Study

1.0 STUDY PURPOSE

Provide scientific data to evaluate and establish the safety and effectiveness of **CCWS™** in the control of Candidiasis in the human body.

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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
- ✓ 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.

Candida Antibody Blood Panel-The Candida Antibody Panel measures IgA, IgG and IgM Antibodies to *Candida albicans*

Saliva D-arabinitol levels – D-arabinitol is a toxic byproduct of systemic candida and the levels can be quantitatively measured to determine the extent of the infection.

Candida Spit Test (*protocol below*)

Each subject was instructed not to drink or eat anything after midnight the night before this test. Subjects came in first thing in the morning for this test. We had them quickly rinse their mouths with room temperature purified water. Healthcare professionals collected approximately 3cc's of saliva by having the subjects spit saliva into the glass of water purified water. Healthcare professionals monitored each sample for an hour. Subjects will be considered to be positive for candida overgrowth if one of more of the list below was present in the sample:

1. Strings hanging down from the saliva.
2. Heavy-looking saliva at the bottom of the glass.
3. Cloudy specks suspended in the water.

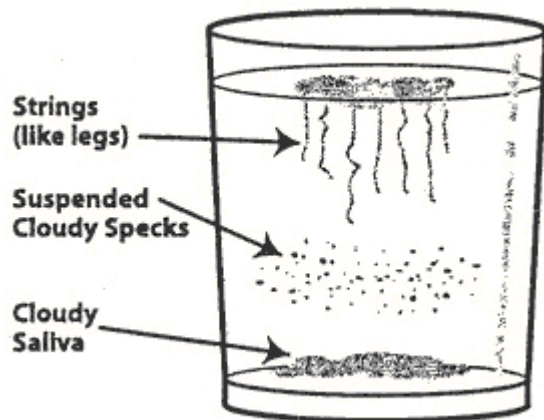
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2.2 PROTOCOL

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 was then entered into the study groups.

History and symptoms questionnaire were completed by each subject on Visit 1.

Symptoms questionnaire was completed by each subject on the final day of their study.

The saliva and blood tests listed above were both ran at Baseline and on day 45.

Initial body weight was measured at Baseline and again on the last day of this study.

2.3 TAKING THE PRODUCT

Each subject was instructed on how important it is to take this product as recommended. Recommendations are as follows:

1. For the first 5 days- take 1 capsule 4 times daily with foods containing fats
2. No product for the next 10 days
3. For the next 5 days- take 1 capsule 4 times daily with foods containing fats
4. No product for the next 10 days

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5. For the last 5 days- take 1 capsule 4 times daily with foods containing fats

2.4 SYMPTOMS

Subjects were required to answer a health intake in regards to their current Candidiasis symptoms. Subjects rated their symptoms on a Standard 1-10 scale where 0-no symptoms and 10-severe symptoms that persisted at least 5 days of the week. Subjects filled out the same questionnaire at Baseline and on the final day of the study.

1. Do you feel bloated when you eat?
2. Do you form gas when you eat?
3. Do you experience acid reflux?
4. Do you have brain fog?
5. Have sinus or ear infections?
6. Suffer from fatigue?
7. Have a dry mouth?
8. Have vision changes, blurry, then clear, then blurry?
9. Have constipation or diarrhea or both?
10. Have rashes?
11. Have toenail or finger nail fungus?
12. Have vaginal yeast infections or jock itch?
13. Do you have allergy problems?
14. Do you have headaches?
15. Frequent colds?
16. Do you experience depression?

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2.4.1 EXPLANATION OF SUBJECTIVE SYMPTOM RELIEF

1. Do you feel bloated when you eat?

Answers:

78% of subjects expressed they had this symptom 3-7 times weekly

41% of subjects expressed they experienced relief from bloating after meals after the 30th day of this study. 77% of subjects expressed they experienced relief from bloating after meals on the final day of this study.

2. Do you form gas when you eat?

Answers:

35% of subjects expressed they had this symptom 3-7 times weekly.

14% of subjects expressed they experienced relief from gas after meals after the 30th day of this study. 35% of subjects expressed they experienced relief from gas after meals on the final day of this study.

3. Do you experience acid reflux?

Answers:

14% of subjects expressed they had this symptom 3-7 times weekly.

0% of subjects expressed they experienced relief from acid reflux after the 30th day of this study. 5% of subjects expressed they experienced relief from acid reflux on the final day of this study.

4. Do you have brain fog?

Answers:

86% of subjects expressed they had this symptom 3-7 times weekly.

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27% of subjects expressed they experienced relief from brain fog after the 30th day of this study. 84% of subjects expressed they experienced relief from brain fog on the final day of this study.

5. Have sinus or ear infections?

Answers:

1% of subject expressed they had these symptoms of a sinus or ear infection on day 1 of this study.

1 of subject expressed they experienced relief from sinus or ear infection on the final day of this study.

6. Suffer from fatigue?

Answers:

66% of subjects expressed they had this symptom 3-7 times weekly.

7% of subjects expressed they experienced relief from fatigue after the 30th day of this study. 66% of subjects expressed they experienced relief from fatigue on the final day of this study.

7. Have a dry mouth?

Answers:

16% of subjects expressed they had this symptom 3-7 times weekly.

15% of subjects expressed they experienced relief from dry mouth after the 30th day of this study. 15% of subjects expressed they experienced relief from dry mouth on the final day of this study.

8. Have vision changes, blurry, then clear, then blurry?

Answers:

1% of subjects expressed they had this symptom 3-7 times weekly.

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0% of subjects expressed they experienced relief from changes in vision after the 30th day of this study. 1% of subjects expressed they experienced relief from changes in vision on the final day of this study.

9. Have constipation or diarrhea or both?

Answers:

88% of subjects expressed they had this symptom 3-7 times weekly.

36% of subjects expressed they experienced relief from diarrhea or constipation after the 30th day of this study. 88% of subjects expressed they experienced relief from constipation or diarrhea on the final day of this study.

10. Have rashes?

Answers:

2% of subjects expressed they had this symptom 3-7 times weekly.

1% of subjects expressed they experienced relief from rashes after the 30th day of this study. 1% of subjects expressed they experienced relief from rashes on the final day of this study.

11. Have toenail or finger nail fungus?

Answers:

0% of subjects expressed they had this symptom.

12. Have vaginal yeast infections or jock itch?

Answers:

5% of subjects expressed they had this symptom 3-7 times weekly.

3% of subjects expressed they experienced relief from vaginal yeast or jock itch after the 30th day of this study. 5% of subjects expressed they experienced relief from vaginal yeast or jock itch on the final day of this study.

13. Do you have allergy problems?

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Answers:

18% of subjects expressed they had this symptom 3-7 times weekly currently.

13% of subjects expressed they experienced relief from allergy symptoms after the 30th day of this study. 16% of subjects expressed they experienced relief from allergy symptoms on the final day of this study.

14. Do you have headaches?

Answers:

6% of subjects expressed they had this symptom 3-7 times weekly.

0% of subjects expressed they experienced relief from headaches after the 30th day of this study. 5% of subjects expressed they experienced relief from headaches on the final day of this study.

15. Frequent colds?

Answers:

0% of subjects currently had a cold.

16. Do you experience depression?

Answers:

40% of subjects expressed they had this symptom 3-7 times weekly.

1% of subjects expressed they experienced relief from after the 30th day depression this study. 19% of subjects expressed they experienced relief from depression on the final day of this study.

2.5 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.

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- ✓ 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.

2.6 OTHER PROTOCOL FOR THIS STUDY

- No diet changes were to be made.
- No exercise programs changes were made.

2.7 INCLUSION CRITERIA

- Subjects who signed a written informed consent consistent with required guidelines and meet prior to participation in the trial.
- 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 do have Candidiasis symptoms or who test positive in all of the saliva and blood tests.
- Subjects who are able to follow the protocol as designed by and Fenestra Research Labs
- In generally good health.

2.8 EXCLUSION CRITERIA

- History of head trauma
- History of serious diseases or illness diagnosed at this time.

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- Known moderate to severe renal insufficiency.
- Recent history 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.
- 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.
- Subjects diagnosed as HIV-positive, diagnosed with AIDS, or with any neuromuscular condition including CP, MS, ALS, or Huntington's Chorea
- Subjects with uncontrolled hypertension (e.g. BP>150/100).
- Subjects who have used steroid therapy with-in the last 6-months.
- Subjects 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.

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3.0 CLINICAL DATA ANALYSIS

3.1 GENERAL INFORMATION

Mean Age: 36 ± 5 yrs

Males-99

Females- 101

4.0 CONCLUSION

Based on the data collected from this study **CCWS™** was shown to be safe and effective for human use. There were No reports of allergies, No reactions, and NO interaction with any other product for the duration of this study by any of the subjects.

4.1 THE LIVE PRODUCT GROUP

Based on the saliva and bloods tests completed for this study 80% of the subjects experienced a 99.9% relief from **CCWS™**, the study product. The remaining 20% experienced at least a 50% relief from Candidiasis from **CCWS™**, the study product.

An average weight loss of 11 pounds from day 1 to day 45 was measured in these subjects. *Subjects did not have a change to their diets nor did they have changes to their exercise routines.

100% of subjects stated they felt better on day 45 than they did on day 1 using **CCWS™**, the study product.

100% of subjects stated they had more energy on day 45 than on day 1 using **CCWS™**, the study product.

Based on the data collected from this study **CCWS™** was shown to be safe and effective for human use. There were No reports of allergies, No reactions, and NO interaction with any other product for the duration of this study by any of the subjects.

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4.2 THE PLACEBO GROUP

Based on the saliva and bloods tests completed for this study 100% of the subjects experienced a 0.0% relief from the placebo product. Based on the blood and saliva tests no significant change was seen in any of the subjects in this group.

One subjects lost 2 pounds and one other subject lost 5 pounds in this group. Seventeen subjects had a weight gain of 1-4 pounds during this study. *Subjects did not have a change to their diets nor did they have changes to their exercise routines.

10% of subjects stated they felt better on day 45 than they did on day 1.

10% of subjects stated they had more energy on day 45 than on day one.

4.3 FOLLOW-UP STUDY

The remaining test subjects that did NOT have at least a 98% removal of Candidiasis based on the saliva and blood test we placed into a follow-up study directly following this one. Subjects followed the protocol explained in 2.3 and all of the protocol from this study was followed.

4.4 RESULTS OF FOLLOW-UP STUDY

Based on the saliva and bloods tests completed for both studies 100% of the subjects on the live product now experienced approximately a 99.9% relief from **CCWS™**, the study product.

An average weight loss of 10.5 pounds from day 1 to day 45 in both studies was measured in these subjects. *Subjects did not have a change to their diets nor did they have changes to their exercise routines.

100% of subjects stated they felt better on day 45 than they did on day 1 using **CCWS™**, the study product.

100% of subjects stated they had more energy on day 45 than on day 1 using **CCWS™**, the study product.

Based on the data collected from both studies **CCWS™** was shown to be safe and effective for human use. There were No reports of allergies, No reactions, and NO

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interaction with any other product for the duration of this study by any of the subjects.

Based on these two studies approximately 20% of people taking **CCWS™** may need to do a second round of the product in order to experience the same relief seen here in this study.

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