

**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**  
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### Study Identification

Unique Protocol ID: LASUTH/09/2012

Brief Title: The Safety and Efficacy of Jobelyn in the Treatment of Breast Cancer Patients

Official Title: A Prospective Phase II Randomized, Blinded Study to Demonstrate the Effectiveness of Jobelyn for the Treatment of Breast Cancer Patients.

Secondary IDs: HEALTH FOREVER PRODUCT LTD [Grantor or Funder: LAGOS STATE UNIVERSITY]

### Study Status

Record Verification: October 2016

Overall Status: Recruiting

Study Start: October 2016 []

Primary Completion: October 2017 [Anticipated]

Study Completion: January 2018 [Anticipated]

### Sponsor/Collaborators

Sponsor: Lagos State University

Responsible Party: Principal Investigator

Investigator: Abiodun Popoola [apopoola]

Official Title: CONSULTANT IN THE DEPARTMENT OF ONCOLOGY  
LASUTH

Affiliation: Lagos State University

Collaborators:

### Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved

Approval Number: NHREC04/04/2008

Board Name: Ethics Committee, Lagos State University Teaching Hospital

Board Affiliation: Nigerian National Ethical Board

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Data Monitoring: Yes

FDA Regulated Intervention: No

## Study Description

**Brief Summary:** To determine the effective functionality/potency of Jobelyn as an immunologic and haematologic booster in Breast cancer patients (start-off), thus improving the outlook and the quality of life of such patients generally

**Detailed Description:** Breast cancer is one of the most frequent malignant tumor of women in Nigeria. In Nigeria, among the urban women, the numbers of breast cancer patients were increasing annually, both to aging of the population and increase in age-specific incidences. Case control studies in parts of the country have identified the factors such as null parity, late age at marriage, and late age at first pregnancy are important risk factors. It has also been suggested that western dietary influences changed the lifestyle of urban women could be one of the major causes of the slowly rising incidence of breast cancer in Nigeria. Therefore early detection and search for potential anti-tumour compounds are important in the control of breast cancer. Standard treatment modalities have improved the overall outlook and quality of life for women with breast cancer; however, the fact that more than 50% still succumb to disease highlights the need for new therapeutic approaches and identification of new therapeutic targets.

Jobelyn is made from Sorghum bicolor which grows abundantly in many parts of the world. Major component analysis of the raw materials and the finished product showed that the herbal product contains oligomeric and polymeric proanthocyanidin (OPCs) which are a class of flavonoid complexes. They are also referred to as condensed tannins. They were first discovered in 1948 by Jacques Masquelier, who developed and later patented techniques for the extraction of proanthocyanidin from pine needles and grape seeds. They can also be found in apples, coconut, cocoa beans, black currant, green tea, black tea. Cocoa beans contain the highest concentrations.

In preliminary research, proanthocyanidin was reported to have anti-mutagenic activity. Studies also show that proanthocyanidin antioxidant capabilities are 20 times more powerful than vitamin C and 50 times more potent than vitamin E2. They also work directly to help strengthen all the blood vessels and improve the delivery of oxygen to the cells. Having affinity for cell membranes, they provide nutritional support to reduce capillary permeability and fragility. These they owe to their role in stabilization of collagen and maintenance of elastin.

Oligomeric proanthocyanidin helps in cancer treatment by inhibiting the initiation and progress of cancer cells. This is why according to a study, it was found that Jobelyn water extract had a stronger effect on increasing Cluster of Differentiation 69 expression in Natural Killer cells (higher cytotoxic activity) while Jobelyn Ethyl Alcohol extract had the greatest effect on increasing Cluster of Differentiation 69 expression in Natural Killer T-cells, T-cells and monocytes (activation & proliferation). In addition to its selective cytotoxicity property, oligomeric proanthocyanidin may up-regulate certain apoptosis promoter genes and down-regulate apoptosis-inhibitor genes in cancerous cells.

3-Deoxyanthocyanidins are a rare type of flavonoids restricted to a few plant species. They are the major pigments in flowers of sinningia (Sinningia cardinalis) and are found in silk tissues of certain maize lines. Sorghum is the only dietary source for 3-deoxyanthocyanidins, which are present in large quantities in the bran of some cultivars. Many plants use secondary

metabolites to protect themselves against pathogen attack. In sorghum, this defense response is an active process resulting in the accumulation of high levels of 3-deoxyanthocyanidin phytoalexins in infected tissues. Luteolinidin and apigeninidin are the two major 3-deoxyanthocyanidins. Flavonoids are increasingly recognized for their range of health benefits, such as reducing the risks of cardiovascular diseases and cancers due to their antioxidant, anti-inflammatory, and chemoprotective properties. In particular, anthocyanins and anthocyanidins from different sources were shown to suppress proliferation and induce apoptosis in cancer cell lines. In a recent study, 3-deoxyanthocyanidins were found to have antioxidant properties similar to those of anthocyanins, but they are more stable to power of hydrogen, temperature, and light changes, suggesting that they could serve as an alternative source of natural pigments with nutraceutical properties.

The unique properties of 3-deoxyanthocyanidins may extend to their biochemical activity as well. For example, Shih et al. recently demonstrated that the major sorghum 3-deoxyanthocyanidins aglycons, apigeninidin and luteolinidin, were more cytotoxic to human cancer cells than their anthocyanidin analogues, cyanidin and pelargonidin

Recent research publication confirmed that the variety of Sorghum bicolor from which Jobelyn was produced contained two unique compounds which are being reported for the first time in Sorghum and in nature and these compounds have been tested in vitro for their anti-inflammatory properties using Ibuprofen as control. They showed superior results to Ibuprofen for their safety and efficacy properties. Hitherto, 3-deoxyanthocyanidins which have been known to contain two main compounds, apigeninidin and luteolinidin has now been increased to four compounds, courtesy of the two new additions discovered from the unique Sorghum variety which is the main ingredient of Jobelyn.

Anaemia, commonly defined as a haemoglobin level of <14g/dl in men and <12g/dl in women, occurs in over 30% of cancer patients at any point in time, and its incidence increases with treatment and disease progression. This anaemia could be related to the patient (haemoglobinopathies, gastrointestinal problems, thalassemia, etc.), related to the disease (bone marrow infiltration, bowel resection, hypersplenism, diminished nutritional state) or related to therapy (drug-induced haemolysis, hypoplasia of bone marrow-bearing areas such as the pelvis secondary to radiotherapy, bone marrow and renal toxicity secondary to chemotherapy, etc.). Inflammatory cytokines such as tumour necrotic factor-alpha and interleukin-6, among others, play a major role in the pathophysiology of anaemia in the cancer patient, not only through complex mechanisms of the purely inflammatory situation but also through genetic regulatory aspects of erythropoiesis.

Oxidative stress brought about by overwhelming of the body by free radicals from the disease itself (cancer) and the therapy both contribute to increased haemolysis and immune depression, as these degrade cell linings and disrupt many biochemical pathways. Jobelyn, which contains majorly oligomeric proanthocyanidin, prevent cell membrane damage by disrupting the biochemical formation of free radicals, thus preventing the release of haemolytic inflammatory cytokines.

In tandem, by mopping up free radicals, it would be found useful in delaying the onset of opportunistic infection in cancer patients, which in itself can provoke further haemolysis. However, these functions are still being proven in Human Clinical Trials which has so far been carried out in two research centres in Nigeria, though primarily amongst sickle cell and HIV/AIDS patients<sup>1</sup>. However, this experimental trial is now being extended to cancer patients to assess its usefulness in this condition.

## Conditions

Conditions: Haematological Abnormality

Keywords: Breast Cancer  
Jobelyn  
Sorghum bicolor

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 1/Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Triple (Participant, Care Provider, Investigator)

Allocation: Randomized

Enrollment: 60 [Anticipated]

## Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Jobelyn + Cyclophosphamide-Epirubicin6 Cyclophosphamide- Epirubicin 6 course regimen to be used with Jobelyn	Dietary Supplement: Jobelyn + Cyclophosphamide-Epirubicin6 Jobelyn (dietary Supplement) to be used with Cyclophosphamide-Epirubicin6 Other Names: <ul style="list-style-type: none"><li>• Sorghum bicolor extract</li></ul>
Active Comparator: Placebo + Cyclophosphamide-Epirubicin 6 Routine drugs for treatment of Breast Cancer used with Placebo	Drug: Placebo + Cyclophosphamide - Epirubicin 6 Routine drugs for the treatment of breast cancer to be used with Placebo Other Names: <ul style="list-style-type: none"><li>• Breast Cancer drugs</li></ul>

## Outcome Measures

Primary Outcome Measure:

1. Natural Killer Cells Expression

Evaluation of the expression of activated natural killer cells CD3-CD56+CD69+ after treatment with Jobelyn

[Time Frame: 6 months]

Secondary Outcome Measure:

2. Use of health related quality of life measures tool Safety Fractor-36 and self reporting questionnaires  
Subjects would use form Safety Fractor-36 to score aspects of well-being

[Time Frame: 6 months]

3. Hematocrit Changes

Changes in levels of hematocrit after treatment with Jobelyn

## Eligibility

Minimum Age:

Maximum Age:

Sex: Female

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

Women with histologically confirmed breast cancer who had undergone complete or segmental mastectomy plus axillary node dissection were included

Exclusion Criteria:

Patients were excluded if they had distant metastases residual disease in the breast or axilla other serious medical illnesses, or a previous cancer. Women considering pregnancy or using hormones were excluded

Patients who refuse to sign consent form

## Contacts/Locations

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Newly isolated compounds from West African Sorghum bicolor leaf sheaths Jobelyn® show potential in cancer immunosurveillance DOI: <http://dx.doi.org/10.14312/2052-4994.2016-6>

Links:

Available IPD/Information: