



Traditional antidotes "Kallunk oxide" in the treatment of HIV/AIDS

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Abstract

Immune deficiency is an important problem on HIV/AIDS patients. Traditional antidotes "Kallunk oxide", a Complementary and Alternative Medicine (CAM), could be better restored the immunity in initial stage of HIV type-1 patients. The performed modest phase-1 study was observational, prospective and designs as open label, case- only, randomized, treatment, and efficacy research enrolled with CD3+ and CD4+ T cell counts >450, >250 and <200 cu/mm³ of 20 HIV/AIDS patients between the ages 8 and 55 years from both genders at the Project Site Office, HIRS, Palakkad- Dt, Kerala, India. The participants were received traditional antidotes "Kallunk oxide" treatment and the study includes Lymphocyte cell counts as assessed by Flow fluorescence cytometry analysis. The absolute CD3+ and CD4+ T cell numbers increased in four (4) HIV type-1 patients, as confirmed by the baseline CD4+ T cell counts above 450 cu/mm³, showing above 50% increase after the CAM therapy. This traditional antidotes "Kallunk oxide" treatment boosts initial stage of HIV type-1 patients' immunity.

Keywords: AIDS, Antidote, Kallunk oxide, HIV treatment, Siddha therapy, Traditional Indian Medicine.

Introduction

World Health Organization (WHO) had established that, in developing countries culturally-acceptable traditional medicine shows excellent outcomes in HIV/AIDS treatment (Cachay ER, 2011). The U.S. government's agency, the National Institutes of Health (NIH) had commented in their Funding Opportunity Description that, in many developing countries traditional medicine playing a central role in available and accessible care and prevention strategies, although little research has focused on this important aspect to wipe out the HIV infection (Simone *et al.*, 2007).

"Kallunk oxide" is an ancient treatment relates to Traditional Indian Siddha Medicine (Fritts *et al.*, 2008), which has been handed down by tradition. Siddha medicine (Gogtay *et al.*, 2002) is common among the Tamil people in south of India, and similar to Ayurveda except that it is employed more minerals and metals in its therapies. There are 32 internal and 32 external medicines are included in this ancient system of medicine. Among the 32 internal medicines, this study was selected the top most rejuvenate medicine as "Kallunk oxide" treatment to cure/control of HIV (Ramjee *et al.*, 2007) infection. In Siddha texts, "Kallunk" is defined as an alloyed form of metals and pashanams (consolidated minerals, especially, those could not resist the action of fire) by using secret methods. It is traditionally incinerated by burning cow dung cakes. The end product from this repeated process is reddish color powder as oxide form molecules. It is one of the special features of Siddha medicine and is not known to other medical systems in India or other countries. The preparation of Kallunk oxide relates to some of the alchemical process leading to rejuvenating treatment named Kaya Kalpa by Siddha concept. It is considered as

unique healing agent believes to effective therapy in treating chronic as well as infectious diseases.

This research, Phase-I (Smita *et al.*, 2006) study, was individual investigator initiated project to identify the safety and efficacy (Wilson *et al.*, 2007) of Complementary and Alternative Medicine (CAM) in the treatment of HIV infection. The 20 enrolled Phase-I study participants were initial and chronic groups infected with Human Immune deficiency Virus (Malhotra *et al.*, 2007) HIV type-1. Study aims therapy's potential inhibition of highly productive HIV-1 infection in T cells (Paskaleva *et al.*, 2006) by traditional antidotes "Kallunk oxide" molecules.

Materials and methods

In this modest Phase-I clinical trial, the Principal Investigator recruits only informed consented HIV/AIDS patients. The full oral information about this study as well as the detailed inclusion criteria, as established in the protocol register www.clinicaltrials.gov, was given to the patients and clearly described about antidotes "Kallunk oxide", a traditionally using alternative Siddha medicine in India. Conducted study was Observational (Preeyaporn Srasuebku *et al.*, 2007) and patients Case-Only. In this prospective study, the number of groups/ cohorts was taken into two Arms and 20 HIV/AIDS patients were participated in this study.

The study recruited CD3+ and CD4+ T cell count >450 and >250 cu/mm³ of HIV- infected persons in Wing No.1 group and <200 cu/mm³ of AIDS patients in Wing No.2 group at the Project Site Office, Palakkad - Dt, Kerala, in India. The CD4+ T cells >50, >250, and >450 cu/mm³ were baseline counts and the ages enrolled between 8 and 55 years from both genders (Gupta *et al.*, 2007).

Study had met the inclusion criteria such as: Patients have HIV - infection, Able and willing to use the study

drug, at clinical trial participation, and greater than 8 years old children.

The study had met the predefined exclusion criteria were; medical side effects, pregnant or breast feeding, history of significant cardiac abnormalities or dysfunctions, using antiretroviral therapy drugs, receiving certain drugs or treatments, unable to be followed at a participating clinical site, children of any age less than 8 years old, any serious conditions like severe chronic stage AIDS cases, allergy to any of the study drugs or their formulations, tobacco, alcohol and drug addicting patients.

The drug was traditionally prepared as oral powder therapy, respectively, 100 and 200 mg antidote combines with 0.01 and 0.04 mg highly purified and calcined molecules of "Kallunk oxide". The minimum dose of tolerance had taken as 100.01 mg and 200.04 mg antidotes "Kallunk oxide" molecules, was added to 1/2 cup hot water. This combination therapy (Fiscus *et al.*, 2007) was used once daily dose in five days, as one course, and was continued the second course after 15 days of therapy interval.

The medicine 100.01 mg was given for one child in Wing No.1 group while, rest of 19 HIV- infected adults in Wing No.1 & 2 groups received 200.04 mg. All patients were treated by two course medicine during the period of 5 to 25 days and taken six months to one year follow -up study.

This research study adhered with Helsinki Declaration and conducted from November 2006 to October 2007. This study has been reviewed and approved by the Institutional Review Board IRB00004979, TAMRC-Bio-Medical IRB#1, Approval Number: TAM-IRB-05, and was sponsored by Traditional Alternative Medicine Research, India.

Patients received Siddha therapy in two different times. Safe dose and efficacy of therapy (Manosuthi *et al.*, 2007) were the outcome measures and this time frame was taken a follow - up of six months. No safety issues were designated with these two outcome measures. The patients were not used injection drug and highly active antiretroviral therapy (Morris *et al.*, 2007) Viral Load assay and Cure of opportunistic infections were not carried out by the poor HIV/AIDS Indian people and the resources of this Phase-I studies. ELISA and Western Blot blood tests were used to confirm HIV infection.

Laboratory method

Flow fluorescence Cytometry (Thakar *et al.*, 2006) assay for CD3+ and CD4+ T cell counts, the total lymphocyte counts (Moore *et al.*, 2007), observed values, and reference ranges were assessed by Flow fluorescence cytometry analysis. Laboratory investigations along with other relevant clinical examinations were achieved for final diagnosis with the quality (Mutimura *et al.*, 2007) of the sample as well as the assay procedures used.

Results

Statistically, the higher CD3+ and CD4+ T cell counts were found in four (4) HIV patients after this potent anti HIV treatment. The enrolled baseline CD4+ T cell counts $>450 \text{ cu/mm}^3$ of four (4) HIV patient's CD3+ and CD4+ T cell counts were highly increased after two courses of CAM therapy. The patient's body mass approximately gained 2 to 5 kg and the AIDS patient's appetite and energy also increased. The absolute CD3+ and CD4+ T cell counts were most commonly monitored. Hematological and non-hematological toxicities, as thrombocytopenia, neutrophilia, neutropenia, eosinopenia, lymphocytosis, nausea, fatigue, vomiting and yellow skin color were not found. The Wing No.1 & 2 study group's blood data were analyzed and determined the efficacy of 200.04 mg "Kallunk oxide" dose. Clinical Trials Registration ID: NCT00276991, Registry: www.Clinicaltrials.gov and URL: [http:// clinicaltrials.gov](http://clinicaltrials.gov).

Discussion

The enrolled 20 patients received this traditional antidotes "Kallunk oxide" treatment. The recruitment was executed by media advertisement and the enrolled participants were selected from Palakkad- District, Kerala state, India. The participants were outpatients followed six (6) site visits after treatment. The patients received this therapy at the project site. The dosage was administered as 100.01 mg and 200.04 mg. The study enrolled 10 male and 10 female HIV/AIDS (Kumar *et al.*, 2006) patients. The study was carried out one test method and equipment to ensure the T- Lymphocyte enumeration. The variations on study results from different laboratories were minimized the error as 20% to 30%. Patients with the baseline CD3+ and CD4+ T cell counts $>450 \text{ cu/mm}^3$ were randomized.

Patients received Siddha therapy in two different times. Safe dose and its effectiveness were the outcome measures and this time frame was taken a follow - up of six months. No safety issues were designated with these two outcome measures. Viral Load assay and Cure of opportunistic infections were not carried out by the poor HIV/AIDS Indian people with resource-limitation (David M Moore *et al.*, 2007) settings of this Phase-I studies.

Four HIV patients responded to the therapy well. A 29 years old female whose previous absolute CD3+ T cell counts were noted as 1748 cu/mm^3 and her total CD4+ T lymphocyte counts were evaluated as 580 cu/mm^3 . After therapy, the enrolled CD3+ T cell counts increased to 2253 cu/mm^3 and the CD4+ T cell counts changed to 663 cu/mm^3 .

HIV- infected 8 years old female child whose previous CD3+ T cell counts were noted as 2917 cu/mm^3 and CD4+ T cell counts were 607 cu/mm^3 . After two courses of medicine, her CD3+ T cell counts increased to 3032 cu/mm^3 and the CD4+ T cell counts to 1304 cu/mm^3 .

HIV infected woman (34 years old) (Jeannie S Huang *et al.*, 2006), whose CD3+ T cell counts were 1321 cu/mm^3 and CD4+ T cell counts 635 cu/mm^3 . After the

medicinal therapy, the CD3+ T cell counts changed to 2865 cu/mm³ and the CD4+ T cell counts increased to 868 cu/mm³.

A 38 years old adult whose absolute CD3+ and CD4+ T cell counts were noted as 2049, and 756 cu/mm³, respectively, and after this treatment, the CD3+ T cell counts increased to 2420 cu/mm³, and the CD4+ T cell counts to 963 cu/mm³.

The study found a slow immune response to antidotes "Kallunk oxide" occurred in <50 cu/mm³ of CD4+ T cell counted AIDS patient (Vidal *et al.*, 2007) and the study confirmed the efficacy of 100.01mg and 200.04 mg minimum doses of this treatment. The study observed that, the initial stage HIV- infected patients rapidly responded to antidotes "Kallunk oxide" than the AIDS patients.

The administration of treatment, dosage, and dose of frequency were limited. The given minimum doses were being first activated in the peripheral blood than lymph nodes and tissues. The background of the dormant stage virus and its replicating activities were being stimulated in HIV- positive patients in order to block the full immunological benefits. Further more efficient research study is needed.

Before this treatment, the Median of 20 participant's absolute CD4+T cell counts were noted as 306.05 cu/mm³ and after treatment, the CD4+T cell counts observed as 352 cu/mm³. The difference on median CD4+ T cell counts was found at 45.95%.

Before this therapy, 20 patients median absolute CD3+ T cell counts were noted 1285.05cu/mm³. After treatment, the CD3+ T cell counts were observed at 2336.05cu/mm³. The difference on median CD3+ T cell counts was determined at 1051 cu/mm³.

In addition, in five patients previous absolute CD4 +T cell counts (Thakar *et al.*, 2006) below 350 cu/mm³ or less and their CD3+ T cell counts increased by six month's study period. A 38 years old adult patient's CD4+ T cell counts increased at 963 cu/mm³ and, especially, CD4 percentage (Yasmin Pirzada *et al.*, 2006) was noted 26.67cu/mm³. The absolute CD3 and CD4 T cells were substantially improved in sixteen (16) HIV/AIDS patients at 86% and 45.05%.

Baseline Study

- Most enrolled patient's HIV positive (Ramjee *et al.*, 2007) background was above 4 years
- All participants received Oral powder form medicine
- No known toxicity (skin rash, hepatotoxicity, hepatitis-related symptom etc) associated with traditional antidotes "kallunk oxide".
- All patients not strictly adhered the controlled diet protocol.
- Short- term toxicities were not encountered.
- All patients had received this therapy 10 minutes before sunrise.

- Enrolled participants had no HIV-associated (Lichtenstein *et al.*, 2007) opportunistic illnesses (Patrick S. Sullivan *et al.*, 2007).
- All patients had accessed overall clinical benefit from this study.

Conclusion

The study evaluated the traditional antidote "Kallunk oxide", a Complementary and Alternative Medicine (Goldrosen, 2004) and its treatment boosted the immunity in 4 (four) initial stage HIV type-1 patients with the baseline CD4 + T cell counts >450 cu/mm³.

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