

Full Length Research Paper

A study of the use of trinity immunobooster (Trino IB) in HIV sero-positive persons without aids

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This study shows that Trino IB is an efficient preparation for maintaining the health of the HIV sero-positive persons and for preventing the progression of their disease to the AIDS phase.

Key words: Trino IB, HIV sero-positive persons, CD4 count, alpha lipoic acid, oleuropein.

INTRODUCTION

Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) have continued to be topical and current issues globally, especially in Africa, since their debut over a quarter of a century ago. In Africa, HIV and AIDS have become very important issues surfacing regularly in significant discussions on education, economy, security and the general health of the population. It seems no issue of importance could be discussed comprehensively without paying due attention to and including HIV and AIDS.

Unfortunately, for socio-economic reasons, Africa, which bears the heaviest burden of the pandemic, is also the least equipped of the continents to deal with the crisis comprehensively. For example from the work of De Cock et al. (1991), it has been shown that in Abidjan major city hospitals, the fatality rates (deaths per 1000 admissions) in adult medical patients increases by 54% between 1983 and 1988, with increases of 106 and 98% in men 20 - 29 and 30 - 39 years of age, respectively and 199 and 24% in women of the same age range. Despite the continent's potential riches, it is, in reality, largely populated by impoverished people without the economic strength, knowledge backed with appropriate skills and technology to deal with the challenges posed by HIV and AIDS.

Although Africa has the highest incidence of morbidity and mortality due to HIV and AIDS, it is currently contributing the least qualitative efforts to stop the spread

of the pandemic and mitigate its impacts. The continent is at the receiving end of the benevolence of others in terms of research, money and drugs to limit the spread of the pandemic and reduce its negative impacts on the lives of the infected and affected people.

To date, despite all the large number of people involved in its research and care and in spite of the huge amounts of money being spent on the pandemic, no credible cure of HIV infection seems to be in sight. It is rather curious and absurd, though, that a disease that is virtually 100% preventable continues to rampage human populations with impunity.

Many research efforts are continuing to address the challenges being posed by HIV and AIDS all over the world. For example Hurley et al. (1997) has shown that Needle-exchange programmes are potentially a key strategy for containing the spread of HIV infection among injecting drug users. This brief report is a contribution to the ongoing efforts towards finding effective means to checkmate the spread of HIV and AIDS and to mitigate its negative impacts.

It is clear that one of the main modalities by which HIV produces its devastating effects on human health is through the suppression of the immune system of infected individuals. This is achieved mainly through the destruction of the CD4 lymphocytes. Burchan et al. (1991) have indicated that both CD4% and rate of change of CD4% in an individual had significant prognosis value in determining AIDS-free survival time. The knowledge that HIV virus depletes CD4 count of HIV sero-positive people progressively is being utilized in this

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study.

Trino IB, a proven immune boosting preparation in animal studies (Oloke, 2008), is administered to HIV sero-positive persons to observe the effects it might have on their immunity. It is a natural product, the identified active components of which are alpha lipoic acid and oleuropein among, possibly, other yet to be recognized compounds (Oloke, 2008). Alpha lipoic acid and oleuropein are anti-oxidants known not only to boost the immune system by activating macrophages and neutrophils but also by inactivating HIV virus (Merin et al., 1996; Baur et al., 1991; Suzuki et al., 1992; Coni et al., 2000; Ziegler et al., 1995).

This short communication is a report of the preliminary findings in ten out of thirty HIV sero-positive individuals, recruited for the study, who have taken Trino IB for at least three months. We felt compelled to share the information from the study now, before completing it, in view of the findings which we consider significant.

METHODOLOGY

Trino IB is formulated as a liquid preparation administered to participants orally. Animal studies have proved that at the dosage given to the people participating in the study, the preparation is completely nontoxic (Oloke, 2008). Till date, no single adverse events traceable to the preparation, has been reported by any of the volunteers participating in the study. The preparation is administered orally to HIV sero-positive volunteers for 3 to 6 months. A dosage of 5 ml per day is used. Each volunteer is taught to use a 5 ml syringe to measure accurately 5 ml of the drug before leaving the clinic. The preparation is to be taken each day, thirty minutes before breakfast.

The study began after due approval was obtained from the ethics committee of the Baptist Medical Centre, Ogbomoso where the study was undertaken. Written and signed informed consents were sought and obtained from each volunteer before they were included in the study after they had been diagnosed and confirmed as being HIV sero-positive.

All participants, involved in the study, are HIV sero-positive people whose infection has not reached the AIDS phase. No pregnant woman was included in the study and all participants were adults older than 21 years.

The screening tests carried out are mainly the ELISA method, GENE 2 or DETERMINE rapid tests methods. Confirmation test was done by the Western Blot method. None of the patients found positive by screening tests was returned negative through the confirmation test.

Since the highly active anti-retroviral therapy (HAART), introduced in 1995, remains the standard treatment for HIV infection (Barlett, 2009) especially for patients who have reached the AIDS phase of the infection, we deliberately chose to exclude full blown AIDS patients, regardless of their CD4 counts and those with CD4 counts below 200 per micro-liter, from the study.

Apart from counseling infected persons on how to live positively with the virus, including maintaining a high standard of personal sanitation and hygiene, consumption of clean and balanced diets and regular recreation with relaxation, participants were also counseled to refrain from behaviors which could cause the spread of their infection to other people as well as those that could make them acquire viruses from other infected persons.

The CD4 count of each participating volunteer was determined before they were commenced on Trino IB and the count was

repeated every three months. Any inter-current infections or ailments were reported at the clinic and were promptly and adequately treated.

RESULTS

Of the thirty volunteers who have been recruited so far for the study, sufficient data on ten of them are currently available for analysis, each having had at least two CD4 counts at three months intervals since they began to take Trino IB.

All participants had an increase of CD4 count, at least 36%, after they had been on treatment for 3 months; the least increase being 36.2% (Table 1). Three of the participants had increases above 45% while six of the ten had at least 50% increases (Table 2). It worthy to note that the highest percentage increases of 154 and 171% were recorded by participants who had being on the preparation for six months, possibly suggesting that cumulative benefits continues after three months of therapy (Figure 1). The means for the basal and Current CD4 counts are 313 (SD 27.96) and 556.10 (SD 61.04) (Table 1). Using paired sample T-Test, the means were significantly different ($P < 0.05$).

DISCUSSION

Without a doubt, HIV infection is one of the most important plagues that have ever afflicted man. HIV and AIDS crisis is a true pandemic because there is not a single country on the globe that has not reported cases of the infection among its population. The significance of the HIV infection lies, not only in the fact of its global spread, but also on the reality that this plague, unlike any other before it, has defiled and is still defiling all human efforts to curtail it. This is in spite the fact that the pandemic is happening now at a time when human knowledge seems to be at its zenith, since the beginning of human history. It is no small wonder then that the pandemic continues its rampage, unabated, in spite of the high concentration of human efforts and resources of money, technology and materials being committed to it (Patrick, 2004).

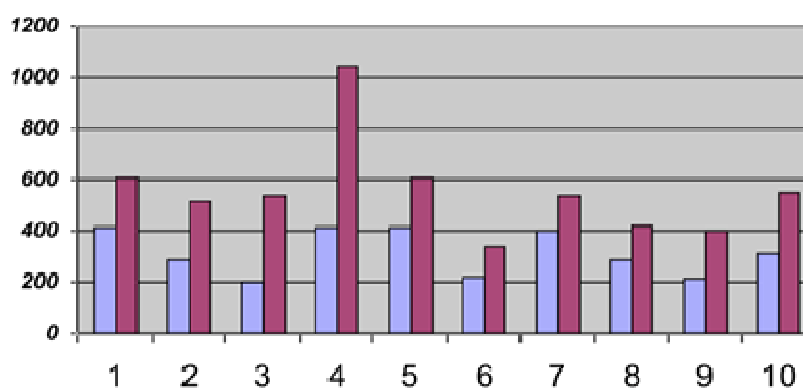
No cure has yet been found for treating HIV infection. There is, as yet, no existing medical treatment that can completely eradicate HIV from the body once it has infected human cells (Barlett, 2009). Trino IB is certainly not a cure, but if the on-going study should confirm the initial findings, the preparation may well prove to be one of the most significant discoveries in man's efforts to find respite from the unrelenting march of the pandemic. It could as well be a major breakthrough in the continuing efforts to find a way out of the many challenges posed by the pandemic. This is more importantly so as the preparation is free from side-effects; no single participant has reported a single adverse event while on it. In addition, the preparation is comparatively cheap as one month's

Table 1. CD4 counts of 10 participants on Trino IB at 3 and 6 months.

S/N	Card no.	Basal CD4 count	Date	Current CD4 count	Date	Remarks (months)
1.	UC-07-1007	410	January 25,2007	605	April 26, 2007	3
2.	UC-06-2679	283	December 15, 2006	515	March 8, 2007	3
3.	UC-05-2127	199	December 7, 2006	540	June 7, 2007	6
4.	UC-05-0358	412	November 30, 2006	1,045	May 31, 2007	6
5.	UC-07-1007	410	January 18, 2007	605	April 19, 2007	3
6.	UC-07-1270	216	January 18,2007	340	April 19, 2007	3
7.	UC-06-1270	397	December 14, 2006	540	June 14,2007	6
8.	UC-06-2241	286	October 12, 2006	420	April 12, 2007	6
9.	UC-06-2163	210	November, 2006	401	February, 2007	3
10.	UC-06-2169	309	November 23, 2006	550	May 24, 2007	6

Table 2. Percentage increase in CD4 counts among 10 patients.

% Increase CD4	Months
47.56	3
81.97	3
171.35	6
153.64	6
47.56	3
57.40	3
36.02	6
46.85	6
90.95	3
77.99	6

**Figure 1.** Comparing the CD4 counts in 10 patients at 3 months (blue bars) and 6 months (red bars).

supply costs only about one thousand Naira (N1,000), which is less than \$6 per person per month. On the other hand, an average person on basic anti-retroviral drugs' (ARDs) combination at the moment would have to spend no less than twenty thousand Naira (N20, 000) per month if they have to purchase the drugs. Another clear

advantage of using Trino IB for HIV infected persons is the ease of administration of the preparation orally, once daily. In addition, the total annual operating cost for just giving advice alone in controlling AIDS in Nairobi among HIV-positive female prostitutes is as high as \$12 for each case of HIV infection prevented (Moses et al., 1991). The

use of Trino IB in preventing HIV infected person to progress to AIDS state gives far better result than the so called Needle-exchange programmes which is a key strategy for containing the spread of HIV infection among injecting drug users (Hurley et al., 1997).

Acquired Immune Deficiency Syndrome is the final stage of a chronic infection with HIV. In the body of HIV infected persons, the virus invades the cells of the immune system, especially the lymphocytes called T cells. Particularly vulnerable to HIV attack are specialized helper T cells known as CD4 cells. When HIV enters a CD4 cell it commandeers the genetic tools in the nucleus to manufacture new HIV virus. In the process the newly formed HIV viral particles destroy the CD4 cell. The loss of CD4 cells endangers health of sero-positive individuals because these cells help other types of immune cells respond to invading organisms (Barlett, 2009). The average healthy person has over 1,000 CD4 cells per microliter of blood. In a person infected with HIV, the virus steadily destroys CD4 cells over a period of years, diminishing the cells' protective ability and weakening the immune system. When the number of CD4 cells drops to 200 cells per microliter of blood, the infected person becomes vulnerable to AIDS-related opportunistic infections and rare cancers, which take advantage of the weakened immune defenses to cause disease.

The observation that none of the participants in this study dropped their CD4 counts during the duration of treatment but that all increased their counts is significant. If this observation is sustained, Trino IB may prove a remarkable weapon in the fight against HIV and AIDS. It could mean that HIV sero-positive persons, without full blown AIDS, need no longer to progress to the AIDS phase of their infection and having to be placed on very expensive ARVs with their potential for serious side-effects and development of the infective agent resistance to the drugs. Happily, since Trino IB is not an anti-viral agent, in the conventional sense, the possibility of HIV virus becoming resistance to it would be very remote. It should be noted also, that whereas we have not studied the use of the preparation on AIDS patients, for ethical considerations, there is a strong possibility that AIDS patients would benefit equally from taking Trino IB as the HIV infected persons without AIDS. It is our expectation that the benefits of immune boosting observed among participants in this study, will apply to AIDS patients as well. Perhaps, the use of Trino IB, alone or in combination with standard ARVs, for treating AIDS patients, may prove to produce an equally gratifying result as we have observed in this study. It is also possible that there could be a beneficial synergy in the use of a combination of standard ARVs with Trino IB.

The prospects are there that Trino IB could prove to be capable of stopping the progression of infection in millions of HIV infected people from progressing to the AIDS phase. The huge reduction in the cost of care, especially in economically challenged communities and lightening of suffering

that infected and affected people experience will be gratifying indeed.

We recommend, therefore, that further studies be conducted to verify the claims in this brief report that Trino IB is an effective and cost beneficial immune modulating preparation that enables HIV infected persons to stimulate their own immune system to check the devastating effects of the infection. The ability of Trino IB to effectively assist HIV infected persons to increase their CD4 count is not totally unexpected as the active components are known inhibitors of HIV (Oloke, 2008).

Conclusion

In conclusion, we have reported in this short communication, our initial findings on ten volunteering HIV positive participants, who have taken the preparation Trino IB for 3 to 6 months. All the participants, by the virtue of their increases in CD4 counts, have been found to have benefited significantly from the preparation. We conclude, therefore, that Trino IB is an efficient preparation for maintaining the health of the HIV infected persons and for stopping the progression of their disease to the AIDS phase. There is also a very good prospect that other patients with diverse immunosuppressive diseases, including diabetes mellitus, could benefit from the use of Trino IB (Patrick, 2004).

We recommend more sophisticated studies involving more participants including double blind, placebo controlled studies and even comparative studies of Trino IB alone or in combination with standard anti-retroviral drugs, in both HIV infected persons and AIDS patients, in many centers to confirm or otherwise the observations we have made in this study.

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