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Clinical Trial of *Medicinal Synthetic Aluminum-Magnesium Silicate* (Antivirt®) on Viral Loads and CD4-Lymphocytes Counts of HIV/AIDS Patients

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Abstract

For clinical trial of *Medicinal synthetic Aluminum-magnesium silicate* (MSAMS, Antivirt®), on viral loads and CD4-lymphocytes counts of HIV/AIDS patients, 10 volunteers were treated. Their blood samples were tested for viral loads and for CD4-lymphocytes counts, before the treatment and every 4 weeks during the medication. The regimen was: MSAMS (50 mg/kg), MSAMS-stabilized Ampicillin trihydrate (7.5 mg/kg) and immunace extra protection® (1 tablet/day), for 4 weeks. Then, it was reduced to 50 mg/kg (MSAMS) and the immune stimulant. When their viral loads become undetectable, they would be treated for additional 4 weeks. Initially, the Antivirt®-regimen appeared to worsen both HIV infection-load and immune deficiency but later relieved them. Patients' mean-viral load increased (P = 0.020), from 1820.30 ± 868.75 to 2855.90 ± 960.98, after 4 weeks before reducing (P = 0.030) to 1565.20 ± 743.17, after 8 weeks. Similarly, their mean-CD4-lymphocytes count reduced (P = 0.008) from 496.80 ± 194.39 to 263.90 ± 149.26, after 4 weeks before improving (P = 0.001) to 507.90 ± 133.19, after 8 weeks.

Keywords

Antivirt®, *Nanoparticles*, Destroying Infected Cells, Unmasking "Hidden Infections", Mopping-Out HIV

1. Introduction

Molecules of Aluminum-magnesium silicate (AMS) are made of *Nanoparticles* [1] [2] which have negative

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electrical charges on their surfaces and positive charges on their edges while HIV has net positive electrical charges [3]. Abnormal (cancer and infected) cells are negatively charged [4]. Therefore, *Nanoparticles* of AMS prevent attachment of HIV to its hosts' cells, by electrostatic-bonding of their negatively charged surfaces to positive charges on the virus. Thus, replication of the virus is inhibited [5] and its particles, mopped out. The *Nanoparticles* also adsorb onto HIV-infected cells by attraction between their positively charged edges and negative charges on abnormal cells. They destroy the infected cells by the mechanism AMS disintegrates drug-capsules [1]. So, "hidden HIV infections" are unmasked. As *Nanoparticles*, they have access to HIV and HIV-infected cells in all organs/tissues. When 100% of population of HIV, infecting a patient is mopped out, the infection would terminate.

Immune deficiency means that number of blood lymphocytes is significantly less than normal [6]. So, AIDS is not a clinical abnormality but a hematological deficit. Since lymphocytes are responsible for immunity, when they become significantly fewer than normal, patients can no longer mount enough immune responses. Therefore, most symptoms associated with HIV/AIDS are those of secondary infections prevalent in each patient`s environment. For that, use of symptoms to assess outcome of treatment of the disease is not reliable.

Antibodies to HIV take three to six weeks, from date of infection, to appear in blood [7]. Also, antibodies can remain in blood of recovered patients for many months after termination of viral infections. Therefore, use of presence of antibodies to determine HIV status of persons can give both false negative and false positive results.

On the other hand, even when antibodies and symptoms of infection are not detectable in HIV-positive individuals, there is increase in their viral loads and decrease in their CD4-lymphocytes counts. During the infection's phase of virus-set-point, when viral loads remain stable, depletion of CD4-lymphocytes still continues [7]. So, combination of determination of viral loads and determination of CD4-lymphocytes counts is a reliable measure of rate of the infection and so, is good for routine monitoring of its pathogenesis and for appraisal of efficacy of antiretroviral therapies.

Aluminum silicate $\{Al_4(SiO_4)_3\}$ and Magnesium silicate $\{Mg_2SiO_4\}$ are medicines, already in use, for oral medication of animals and humans. To get a purer form of AMS$\{Al_2Mg_3(SiO_4)_3\}$ these two medicinal minerals [8] were reacted [9]: $\{Al_4(SiO_4)_3 + 3Mg_2SiO_4 \rightarrow 2Al_2Mg_3(SiO_4)_3\}$. Dextrose monohydrate was formulated with the *medicinal synthetic* AMS (MSAMS, **Antivirt®**), to carry its molecules, by active transport [10], across mucous membranes of the gastro-intestinal tract, into blood which carries them to all organs/tissues.

The MSAMS has inhibited HIV, *in vitro* [11] and cured animals infected with *Paramyxoviridae*, *Parvoviridae* and *Birnarviridae* viruses [12]-[14]. A histopathologic study showed that it inhibited activities of *Canine parvovirus* at organs-level and in different body-systems of infected dogs [14]. Antivirt® was therefore used for clinical trial on volunteer HIV/AIDS patients.

2. Materials and Methods

A formulation of the MSAMS and Ampicillin trihydrate (Antivirt A®) and a formulation of the MSAMS alone (Antivirt B®) were made for the clinical trial. To enhance immune responses of patients Vitabiotics' immunace extra protection® was used. Journal publications which reported that AMS is a safe medicine and those that reported antiviral effects of the MSAMS were used to counsel HIV/AIDS patients. Patients who became convinced that the Antivirt ® is safe and can lead to cure of HIV/AIDS, applied through their physicians, for the clinical trial.

Ten volunteers were placed on oral medication with Antivirt® A for 4 weeks, at dose rates of 50 mg of the MSAMS/kg body weight and 7.5 mg of MSAMS-stabilized Ampicillin trihydrate/kg body weight, daily. Thereafter, they were on Antivirt® B for another 4 weeks, at dose of 50 mg/kg, daily. Each of the patients was also placed on the immune enhancing drug (1 tablet daily), throughout period of the treatment. Blood samples from each patient were tested for viral loads (HIV) and for CD4-lymphocytes counts, before the treatment and every 4 weeks. Means of the viral loads and CD4-lymphocytes counts: before treatment, after treatment for 4 weeks and after 8 weeks were compared for statistical differences, by Analysis of variance.

3. Results

Viral loads of the patients increased ($P = 0.020$) initially, from a mean of 1820.30 ± 868.75 to 2855.90 ± 960.98 (56.89%) after 4 weeks and then reduced ($P = 0.030$) to 1565.20 ± 743.17 (45.20%) after 8 weeks. Also, CD4-lymphocytes counts per ml of plasma of HIV/AIDS patients treated with the Antivirt® reduced ($P = 0.008$) in-

itially, from a mean of 496.80 ± 194.39 to 263.90 ± 149.26 after 4 weeks of the treatment and then improved (P = 0.001) to 507.90 ± 133.19 after 8 weeks (**Table 1** and **Table 2**).

4. Discussion

For a treatment to achieve permanent cure of HIV/AIDS, it should terminate the viral infection and improve CD4-lymphocytes counts of patients, to at least 1000/ml. So, the significant decrease (P = 0.030) in mean viral load and the significant increase (P = 0.001) in mean CD4-lymphocytes count after 8 weeks of this trial-treatment, indicate that the Antivirt® is potentially, an effective antiretroviral medicine.

The 45.20% reduction in mean viral load, achieved when the patients were treated for 8 weeks is similar to initial rate of reduction got when the treatment was for 6.67 ± 2.31 weeks, in an earlier trial-treatment. When the duration was prolonged to 10.40 ± 6.10 weeks, in that earlier trial, rate of viral load-reduction improved, to 98.61% [15]. So, if treatment of HIV/AIDS patients with Antivirt® is continued, long enough, it may be possible to achieve termination of the infection (100%).

Table 1. Viral loads of HIV/AIDS patients, on clinical trial of the *Medicinal synthetic Aluminum-magnesium silicate* (Antivirt®), after eight weeks of the treatment.

Duration (weeks):	0	4	8
1	895	1384	1026
2	2830	3640	2411
3	1052	1695	986
4	3359	4620	3021
5	1630	2822	1040
6	1126	2642	946
7	1056	2300	1000
8	1565	2672	1200
9	1998	3622	2000
10	2692	3162	2022
Mean	1820.30 ± 868.75	2855.90 ± 960.98	1565.20 ± 743.17

Table 2. CD4-lymphocytes counts of HIV/AIDS patients, on clinical trial of the *Medicinal synthetic Aluminum-magnesium silicate* (Antivirt®), after eight weeks of the treatment.

Duration (weeks):	0	4	8
1	789	566	780
2	300	120	423
3	628	295	574
4	270	114	360
5	550	220	491
6	601	321	640
7	750	361	530
8	450	380	522
9	340	160	399
10	290	102	360
Mean	496.80 ± 194.39	263.90 ± 149.26	507.90 ± 133.19

The results show that inverse relationship exists between viral loads and CD4-lymphocytes counts, in HIV/AIDS patients, such that, as viral loads reduce, CD4 counts improve. So, all that may be required to cure both HIV infection and AIDS could be to continue the Antivirt® treatment, long enough.

Reason termination of HIV infections is not achieved with existing antiretroviral therapies (ARTs) is that their molecules are too large to cross physiological barriers. For that limitation, they do not reach HIV infections "hidden" in some cells. So, even when viral loads become undetectable in blood of treated patients, the infection may still remain "hidden". Antivirt® is made of *Nanoparticles.* So, unlike the other ARTs, it crosses physiological barriers to reach HIV and HIV-infected cells in organs/tissues. And since it acts by a physical effect (mopping out HIV), the medicine is safe for prolonged treatment, till termination of the infection is achieved.

Apparent worsening of the HIV infection (increased viral loads) and of the AIDS (reduced CD4-lymphocytes counts) after treatment for 4 weeks, was because the test for viral loads does not detect "hidden infections". So, when the Antivirt® destroyed infected cells and unmasked "hidden infections" in this trial-treatment, more HIV particles became detectable by the test. Infected lymphocytes among cells destroyed, account for the initial reduction in number of CD4-lymphocytes. The increase, in mean-viral load, is also a proof that "hidden HIV infections" have been unmasked. So, when the treatment achieves 100% elimination of HIV-load in blood, the infection would have been terminated.

Apart from its antiviral effects, the MSAMS stabilizes antimicrobials, to improve their efficacy [16]. This means that secondary infections would also be effectively treated. Since 7.5 mg/kg (75% of dose) of the MSAMS-stabilized Ampicillin was used in the treatment, side effects of the drug may have been minimized [17] so that enhanced immune responses also acted in synergy with antiviral effects of the Antivirt® [15].

5. Conclusion

It has therefore been concluded that: since the Antivirt® unmasks "hidden HIV infections"; since it has access to all organs/tissues and since the regimen encourages effective treatment of secondary infections and enhances patients` immune responses, it may lead to permanent cure of HIV/AIDS patients.

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