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Medicinal synthetic Aluminum-magnesium silicate {$Al_4(SiO_4)_3 + 3Mg_2SiO_4 \rightarrow 2Al_2Mg_3(SiO_4)_3$} normalizes immunity and terminates HIV-infections

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Abstract

After three months` trial of Medicinal synthetic Aluminum-magnesium silicate (MSAMS, Nanoparticles) for antiretroviral efficacy, CD4 counts of treated patients increased (P<0.05) from 151.20±42.56 to 458.60±89.55 and their viral loads decreased (P<0.05) from 88,333.33± 3609.01 to 4,127.67±680.2. After four months, CD4 counts of patients who were on existing ARVs before the trial, dropped to 130.50±20.50 and their viral loads rebounded from undetectable (<20) to 2, 100,000 ±9 00,000 but the CD4-increases and viral loads-decreases continued in patients who were not on any ARV before the MSAMS so that by twelfth month, their viral loads became undetectable. It appears, the existing ARVs achieve relief of symptoms by flushing HIV from blood while tissues remain infected. That may be reason, HIV-viremia rebounds whenever treatment with existing ARVs is discontinued. MSAMS` antiviral mechanisms include viral-mopping, immune-stimulation and destroying infected cells (unmasking "hidden infections"). Synergy between immunity and continuous pathogen-mopping would terminate any infection.

Keywords: Nanoparticles; Opposite electrical charges; Normalizing immunity**;** Unmasking "HIV infections"; Infections-termination

Abbreviations: MSAMS: Medicinal Synthetic Aluminum-Magnesium Silicate`S; HIV: Human Immune Deficiency Virus; AIDS: Acquired Immune Deficiency Virus; AMS: Aluminum-Magnesium Silicate; ARVs: Anti-Retroviral Medicines; CD4: Cluster of Differentiation 4.

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Introduction

HIV/AIDS, an immune deficiency (AIDS) disease caused by infection of the Human immune deficiency virus (HIV) is a big health challenge, especially in Africa and Asia [1-5]. The infection is regarded as interminable and the disease, "incurable". Reasons, HIV-infection has been interminable and outcomes of clinical trials of MSAMS on HIV/AIDS patients are subjects of this article. Small sizes of viruses allow them access to cells that are inaccessible to medicines [6-8]. So, antiviral medicines require immunity to achieve termination of infections. HIV destroys lymphocytes which are responsible for general immune response to infections. Lymphocytes play no role in sustaining life. So, their destruction does not lead to immediate death. For that reason, HIV-infections are usually chronic. Chronic nature of HIV-infection makes it require prolonged treatment**.** Prolonged medication with antiviral medicines that act by inhibiting biochemistry of viruses causes toxicity (because of similarity between viral biochemistry and biochemistry of human cells). Medicines that work by physical effects need to reach all infected cells before they can terminate infections. Infected cells that are inaccessible to antiviral medicines are the cells termed "sanctuary cells "or "HIV-reservoirs".

In its attempt to eliminate chronic infections, the body generates reactive oxygen species (free radicals) but free radicals destroy both infections and normal cells. That leads to oxidative stress [9]. Under states of immune deficiency and oxidative stress, existing medicines cannot terminate HIV-infections because their active-particles are too big to reach all infected cells and there is not enough immunity to complement their effects. For that reason, HIV/AIDS is seen as mysteriously incurable. Aluminum-magnesium silicate (AMS)-molecules are made of Nanoparticles, 0.96 nm thick (<HIV). This ultra-small size enables them reach all cells. Edges of the Nanoparticles are positively charged and their surfaces, negatively charged [10]. Viruses have electrical charges with HIV positively charged [11]. So, AMS-Nanoparticles mop the virus with their surfaces. Abnormal (infected/cancer) cells are negatively charged [12]. Therefore, the Nanoparticles also bond onto HIV-infected cells with their edges and destroy them. The "sanctuary cells" are also destroyed so that "hidden infections" are unmasked. When all viral-particles invading a patient`s organs/tissues are moped out, their infections terminate. As a silicate, AMS is an immune stimulant [13]. Added to these, it stabilizes antimicrobials. Stabilizing medicines prolongs their bioavailability [14]. Prolonging bioavailability improves efficacy of medicines [15]. With improved efficacy, 75% of recommended doses of antimicrobials achieve desired effects [16-22]. Use of lower doses of medicines for treatments minimizes their side effects. Minimizing side effects of medicines allows for optimization of immune responses.

AMS does not occur as mineral deposits in Nigeria. Therefore, to get the Medicinal synthetic AMS (MSAMS), Aluminum silicate and Magnesium silicate which are also approved medicines [23,24] that are abundant in the country were reacted: $Al_4(SiO_4)_3 + 3Mg_2SiO_4 \rightarrow 2Al_2Mg_3(SiO_4)$ [24-29]. Since AMS is not absorbable, dextrose monohydrate (simple sugar) was incorporated in MSAMS-formulations to convey the electrically charged Nanoparticles across mucous membranes, into blood-circulation, by active transport [30]. For clinical trial of the MSAMS, in addition to the medicine, patients are placed on anti-oxidants (Vitamins A, C, E and/or Selenium) to mop the free radicals in order to relieve oxidative stress. Synergy between antiviral effects of MSAMS (electrostatic mopping of HIV), relief of oxidative stress, improved efficacy of antimicrobials (effective treatment of secondary infections) and enhancement of immune response of patients, leads to termination of both the viral infection and secondary infections, thus resulting to cure for HIV/AIDS. In this repeat-clinical trial of the MSAMS, five HIV/AIDS patients who volunteered are being treated. Two of the patients had been on existing anti-retroviral medicines (ARVs) for many years before the trial while the other three were naïve patients. Effects of the MSAMS-treatment, so far, on their immunity (CD4 counts) and on their HIV-infection levels (viral loads) were compared with results of an earlier trial.

Materials and Methods

For trial of the MSAMS on HIV-patients, it is dispensed to hospitals in Nigeria, to treat patients, under their care, after they have consented. In both this trial and in the earlier ones, the patients were placed on a formulation of MSAMS (63 %) and 10 % Ampicilin trihydrate (Antivirt® A) in the first month. From second month, the treatment changes to a formulation of 73.5 % of the MSAMS only (Antivirt® B). At doses of 7.5 mg/kg for Ampicilin trihydrate and 50 mg/kg for the MSAMS, the patients take 5.4 g of Antivirt® A per day in the first month and subsequently, 5 g of Antivirt® B per day. The treatment continues till a patient becomes HIV-negative (both antibody and antigen) with his/her CD4 counts ≥1,500. Each of the patients also takes anti-oxidants (Vitamins A, C, E and/or Selenium) every day. The Antivirt® is taken at night, at least two hours after meal while the anti-oxidants are taken in the morning, immediately after meal. Once the Antivirt® is taken, the patient does not eat any other thing (except water) till morning. A patient who has need to take oral medicines for any other condition, is advised to take such medicines at least two hours before

the Antivirt® or two hours after the Antivirt®. Their viral loads and CD4 counts are tested for, every month.

Results

Two of the patients who had been on existing ARVs for a long time, before the MSAMS` clinical trial, had their viral loads undetectable (<20) before the trial but their CD4 counts were only 115 and 207 respectively (AIDS). After three months of the trial, their CD4 counts increased to a mean of 458.60±89.55 but dropped to 130.50±20.50 after the fourth month. Their viral loads also rebounded from undetectable to a mean of 2, 100,000± ±900,000 after that fourth month but they remained clinically healthy.

For the three patients who started treatment with the MSAMS, their CD4 counts increased ($P<0.05$) from 151.20±42.56 to 904.00±3.61 after nine months and their viral loads decreased from 88,333.33 ±364.01 to 400.00±0.00. By that Month-9, viral load of one of the patients became undetectable while viral loads of the other two reduced to undetectable level by the twelfth month of treatment.

	Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10
Cd4 count (mean±sem)	496.90±61.47^{ab}	263.90 ±47.20^{a}	462.90 ±47.22^{a} ^{b}	691.70 ±35.74^{b} ^{c}	840.0 ±44.18^{bc}	1007.3±51.70^{c}	1537.10±95.53^{d}	1924.60±78.25^{e}	2707.00±264.96^{f}	2162.71±318.74^{e}	2792.80±276.82^{f}
Viral load (mean±sem)	1820.10±174.80 ^{b}	2741.90±312.39^{a}	1433.00±243.49^{b}	730.80 ±153.67^{c}	325.10±37.88^{cd}	182.20±31.87^{d}	88.70± 18.32^{d}	35.20± 8.55^{d}	15.70 ±5.34^{d}	9.71±3.76^{d}	0.00±0.00^{d}

Table 1: Mean-CD4 counts and mean-viral loads of HIV/AIDS patients treated with Medicinal synthetic Aluminum-magnesium silicate in an earlier trial.

Patient	Month 0	Month 2	Month 3	Month 4	Month 5	Month 9
A	0	88	129	NR	405	899
B	207	359	512	110	DC	DC
C	115	411	500	<151	DC	DC
D	229	501	675	NR	NR	911
E	205	388	477	NR	NR	902
CD4 COUNT (MEAN±SEM)	151.20±46^{a}	349.40±69.53^{ab}	458.60±89.55^{b}	130.50±20.50^{a}	405.00±0.00^{b}	904.00±3.61^{c}

Table 2: Immune responses (CD4 counts) of HIV/AIDS patients being treated with Medicinal synthetic Aluminum-magnesium silicate.
NR: No result; DC: Discontinued

Patient	Month 0	Month 2	Month 3	Month 4	Month 5	Month 9
A	160000	25000	5000	NR	1000	400
B	UD(20)	UD(20)	UD(<20)	1200000	DC	DC
C	UD(20)	UD(20)	UD(<20)	3000000	DC	DC
D	60000	18000	4600	NR	NR	400
E	45000	12000	2789	NR	NR	UD (<20)
MEAN±SE	88,333.33±36094.01	18,333.33±3756.48	4,127.67±680.21			

Table 3: HIV-infection levels (viral loads) of HIV/AIDS patients being treated with Medicinal synthetic Aluminum-magnesium silicate.
NR: No result; DC: Discontinued; UD: Undetectable

Discussion

Electrostatic attraction which is mechanism of antiviral actions of the AMS is a physical effect. So, it does not have adverse effects on animal cells. Also, Aluminum silicate and Magnesium silicate reacted to get the MSAMS are safe medicines that are already in use [22,23]. Therefore, the new medicine is safe for prolonged medication. When antiviral effects of the MSAMS were tested, in vitro [31-37], mean HIV titer of treated specimens increased ($P< 0.05$) from 4.00±1.60 to 14.00±2. 00 at first, suggesting unmasking of "hidden infections". A repeat of the in vitro treatment reduced HIV titer of the specimens ($P> 0.05$) from 14.00±2.00 to 6.50±1.50 which indicated that the MSAMS mopped-out HIV.

In the animal-studies and in earlier trials of antiretroviral efficacy of the MSAMS, in vivo, [38-49], infection loads in patients reduced as length of time for the treatment was prolonged. In one of the human trials viral loads of the patients increased ($P<0.05$) from 498.50±33.37 to 1,072.50±184.55 after 3.75±2.06 weeks before decreasing ($P<0.05$) to 407.33±297.27 after 6.67 weeks and from 24,250.00±15,939.34 to 321.00±229.38 ($P<0.05$) after 12.00 weeks. In another trial, mean-CD4 count of patients reduced ($P=0.008$) from 496.80±194.39 to 263.90±149.26 initially before increasing to 2,792.80±276.82 after 10 months. Mean of their viral loads increased ($P<0.05$) from 1,820.30±868.75 to 2,855.90±960.98, initially, before reducing ($P<0.0.05$) to 0.00±0.00 in that tenth month.

In present study, the two patients who were on ARV, long before the trial, had their HIV-infections suppressed (viral load < 20) before commencing the MSAMS-trial but their CD4 counts were still lower than normal (207 and 115< 500). The low CD4 counts indicate that their HIV infection-levels may not be as low as their low viremia suggested. What was low may be only number of particles of HIV in their blood. After three months of the MSAMS - trial, their CD4 counts started increasing before they crashed again. The crash in CD4 counts coincided with relapse of viremia. That rebound of viremia could not have been a result of treatment-failure. If the treatment failed and the virus started multiplying the viral loads would have risen from less than 20 to hundreds or thousands (not millions in one month). Also, if those millions of copies of HIV per ml of blood (viral load) were active viral-infections, the patients would not have remained apparently healthy. It is possible that the resurgent viruses were "dormant infections" that were unmasked from infected tissues.

MSAMS destroys infected cells as indicated by reduction in CD4 counts in first months of the trials which is always accompanied by increases in viral loads (unmasking "hidden infections"). So, it is possible that the MSAMS-treatment destroyed cells in tissues that were heavily infected, due to long use of existing ARVs to control viremia in order to keep patients apparently healthy. When viral loads increased in previous trials, they later reduced and eventually came to zero. So, if the patients did not discontinue the trial, it is possible that their viral loads would have reduced after getting to peak (complete unmasking of "hidden infections").

With the three patients who were not on ARV before the MSAMS-trial, their CD4 counts continued to increase while their viral loads continued to reduce till they became undetectable (<20). Difference between these patients in whom MSAMS suppressed HIV-infection (undetectable viral loads) and those who started MSAMS-treatment in state of "suppressed" HIV infection is in their immune levels. In those whose viremia later relapsed, they were still suffering from AIDS (CD4 < 500) while in the MSAMS treated patients, the treatment relieved them of AIDS (CD4 ≥ 500). From the earlier trial, one month after viral loads of MSAMS/antioxidants-treated HIV/AIDS patients become undetectable they test negative to HIV-antigen (termination of infection) and their CD4 counts reach 1,500 or more. That high CD4 count is a proof that they are no longer suffering from an immune-deficiency disease. If they were still HIV-infected, their CD4 counts could not have been so high. With ≥ 2,792.80±276.82 CD4 T-lymphocytes per ml of blood (CD4 counts), there would not be hiding places ("sanctuary cells") for HIV.

Conclusion

Failure of existing ARVs to normalize immunity may be reason they are not able to terminate HIV-infections. Since the MSAMS unmasks "hidden infections" and normalizes immunity, synergy between continuous mopping of HIV (treatment) with the Nanoparticles (access all cells) and normalized immunity will terminate HIV-infections and cure HIV/AIDS.

Consent

Each patient gave his/her consent for the clinical trial, to his/her physician.

Ethical Approval

The authors hereby declare that the clinical trial is being carried out in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki, as, operational in Nigeria.

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