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HIV/AIDS Recovery Rates in Male and Female Patients, Treated with *Medicinal synthetic Aluminum-magnesium silicate*

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Authors' contributions

The authors collaborated for the research. Author MCOE synthesized the MSAMS, designed the experiments and drafted the manuscript while authors DA, NKA and TNO administered the treatment and clinically managed the patients. Authors IJO, EK and NUN analyzed the results and processed the manuscript for publication. All the authors read and approved the final manuscript.

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Original Research Article

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ABSTRACT

Aim: Clinical trial of antiretroviral efficacy of *Medicinal synthetic Aluminum-magnesium silicate* **(MSAMS)** in male and female patients.
Methodology: HIV/AIDS patients were classified as, male-patients and female-patients. Each was treated, daily, with MSAMS (50mg/kg) and immunace extra-protection® (1 tablet). They were tested before the treatment and every month, for viral loads and CD4-lymphocytes counts. When their viral loads became undetectable they were tested for HIV-antigens and HIV-antibodies.
Results: Mean pre-treatment CD4-lymphocytes counts of male patients (483.67±93.01) was slightly (P=0.88) less than females` CD4-lymphocytes counts (502.43±82.73) but after 8 months

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males` CD4s proliferated (3696.67±508.54) more (P=0.0040) than females` (2282.86±116.40). The lymphocytosis continued so that by Month-10, females lymphocytes (2992.80±106.54) approximated (P=0.127) males` Month-8 counts. The male-patients tested HIV-negative after 8.00±0.00 months while the females tested negative after 9.71±0.18 months (P=0.00).
Conclusion: MSAMS-*Nanoparticles* terminate HIV-infections by mopping the virus from organs/tissues and elicit lymphocytosis. Synergy between antiviral effect of the Nano-medicine and lymphocytosis cures HIV/AIDS.

Keywords: MSAMS (Positively and negatively charged ends; Nanoparticles, Silicates); Destroys infected ''sanctuary'' cells (negatively charged); Mops HIV (positively charged); Elicits lymphocytosis.

1. INTRODUCTION

HIV/AIDS has become a major health challenge in most countries of the world. Burden of the pandemic is more in India, Nigeria and South-Africa [1-3]. Manifestations of the disease include symptoms, HIV antibodies in blood, shortage of CD4-lymphocytes in blood (lymphopenia) and presence of copies of the viral RNA in blood (viral load).What made HIV/AIDS incurable is small size (110 nm) of its causative agent, *Human immune deficiency virus* (HIV). The small size enables HIV cross physiological barriers to "hide" in cells of the brain, bone marrow and testes, where existing antiretroviral medicines (bigger molecules) cannot reach [4]. Since it destroys lymphocytes (cells responsible for clearing infections from organs that are in-access-able to medicines), nothing was known that could terminate its infections. So, the infection was said to be in "sanctuary"

Aluminum-magnesium silicate (AMS) molecular platelets (*Nanoparticles*) are smaller (0.96 nm thick) than HIV [5]. So, the *Nanoparticles* cross physiological barriers, to act on every organ/ tissue. Their edges are positively charged and their surfaces negatively charged [5] while HIV is positively charged [6] and abnormal (infected/cancer) cells, negatively charged [7]. Therefore, the AMS-*Nanoparticles* mop HIV from all organs/tissues with their surfaces and adsorb onto infected cells with their edges. They destroy the infected cells, by the mechanism AMS disintegrates drug-capsules [5], so that even infections in the "sanctuary cells" are unmasked and adsorbed out. When 100% of population of invading HIV is adsorbed out its infection terminates.

AMS $\{Al_2Mg_3(SiO_4)_3\}$ is not found as mineral deposits in Nigeria but there are large deposits of Aluminum silicate $\{Al_4(SiO_4)_3\}$ and Magnesium silicate $\{Mg_2SiO_4\}$ in the country. These other two minerals are already being used as medicines, for treatment of animal and human diseases [8]. Therefore, for a purer form of AMS, the two medicinal minerals 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 Aluminum-magnesium silicate* (**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]. It has also cured animals challenged with *Paramyxoviridae*, *Parvoviridae* and *Birnarviridae* viruses [12-14].

CD4-lymphocytes` populations (cell counts) decrease in patients as HIV infection progresses. Also, when CD4 counts are improving, viral loads decrease [3]. Recovery from HIV/AIDS, already reported [15-16] resulted from synergy between antiretroviral effects of the MSAMS and lymphocytosis (CD4 counts >1500) that occurred in treated patients. While antiretroviral effects of the **MSAMS** may not vary, since same dose is used, treatment-duration before lymphocytosis and levels of the immune response may vary between patients. It is also possible for treatment-durations before lymphocytosis and/or its levels to vary between sexes. So, this clinical trial has been designed to compare: levels of immune response and durations of treatment before male and female HIV/AIDS patients treated with the Antivirt®- immune stimulants regimen test HIV-negative.

2. MATERIALS AND METHODS

The **MSAMS** was patented by the Nigerian government [9], as broad-spectrum antiviral medicine. For the clinical trial, a formulation of **MSAMS** and Ampicillin trihydrate (**Antivirt®** A)

and a formulation of the MSAMS alone (Antivirt® B) were made. Publications which report that AMS is a safe medicine and publications on antiviral effects of the MSAMS were used to counsel HIV/AIDS patients. Each patient was required to ask his/her physician to read the publications before applying for him/her to participate in the clinical trial.

Ten HIV/AIDS patients who volunteered for the trial, by writing through their physicians, were classified according to their sexes. Each patient was placed on oral medication, with **Antivirt®** A for one month, 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 [17]. Thereafter, they were on Antivirt® B, at dose of 50 mg/kg, daily, till they tested HIV-negative,. To further enhance their immune responses, they were also treated with Vitabiotics' immunace extra protection® (1 tablet, daily), throughout period of the treatment.

Their blood samples were tested for viral loads and for CD4-lymphocytes counts, before the treatment and every month. Means of the viral loads and CD4 counts for each group were calculated, every month. When a patient's viral load became undetectable, he/she was tested by HIV-confirmatory tests (antigen and antibody) and treatment-duration before he/she tested HIV-negative was recorded.

Treatment-durations before individual patients tested HIV-negative were plotted on a graph, against their pre-treatment CD4-lymphocytes counts. From equation of *line of best fit* of the graph, CD4-lymphocytes count that would give zero treatment-duration (no need for further treatment) was calculated. Means of treatment-durations for males and females, their pre-treatment CD4-lymphocytes counts and their CD4-lymphocytes counts just before they recovered (Months 8, 9 and 10) were compared, by the *Students` T-test,* for statistical differences.

3. RESULTS AND DISCUSSION

3.1 Results

All the volunteer-patients were adults. Seven were females and 3 males. Pre-treatment mean-CD4 of the male patients (483.67±93.01) was less than 502.43±82.73 of the females though the two means were not significantly different (P=0.88) but by Month-8, males' CD4-lymphocytes, (3696.67±508.54) improved significantly (P=0.004) more than 2282.86±116.40 of the females. After additional two months treatment (Month-10) CD4 counts of the female-patients (2992.80±106.54) approximated (P=0.127) that males` month-8 count. Lymphocytosis (3696.67/ml) occurred in the males in Month-8 and all 3 of them became HIV-negative. The lymphocytosis (2548.43 /ml) occurred among the females in Month-9 and 2 of them tested HIV-negative. By Month-10, when higher lymphocytosis (2992.80/ml) occurred in the females, all of them became HIV-negative. Pre-treatment viral loads of the male and female patients were 1269 and 2056, respectively but after one month on the treatment they increased to 2386 (88.02% increment) and 3057 (48.69% increment) before decreasing every month till they became zero (Table 3). CD4 count (from equation of treatment-durations on pre-treatment CD4-counts) when HIV/AIDS patients treated with the **Antivirt®** would test HIV-negative (zero treatment duration) was 3613. 33. Treatment-duration (8.00±0.00 months) before recovery in the males was shorter (P=0. 00) than 9.71±0.18 months it took the females to test HIV-negative.

Table 1. Durations (months) of Antivirt® treatment before male and female HIV/AIDS patients tested HIV-negative

Male	Female
8	9
8	9
8	10
	10
	10
	10
	10
Mean = 8.00±0.00	Mean = 9.71±0.18

3.2 Discussion

Increase of HIV loads in both male-patients and the females, following treatment with the MSAMS for one month gave impression that the infection-loads were increasing, instead of reducing. Also in that first month, CD4 counts of the two groups reduced, instead of improving. Steady decrease of the viral loads and improvement of the CD4 counts, after that, indicate that the first month`s results do not mean increases in infection loads but suggest that the *MSAMS-Nanoparticles* destroyed [18] infected CD4-lymphocytes and so, made "hidden" HIV-infections detectable.

Table 2. Pre-treatment CD4-lymphocytes counts of male and female HIV/AIDS patients and the counts at months of their recovery

Month 0		Month 8		Month 9	Month 10
M	F	M	F	F	F
300	789	4680	2210	2720	3122
350	628	3430	2122	2430	2813
601	270	2980	2043	2216	2960
	750		2820	3020	3329
	450		2046	2304	2740
	340		2629	2827	
	290		2120	2322	
Mean = 483.67±93.01[a]	Mean = 502.43±82.73[a]	Mean = 3696.67±508.54[b]	Mean = 2282.86±116.40[c]	Mean = 2548.43±116.00[d]	Mean = 2922.80±106.54[b]

The 88.02% viral load increment in male patients, against only 48.69% in females suggests that more infections were intracellular in males than in females. This difference in percentage of "arrested infections" may reflect in manifestations of HIV/AIDS in the two sexes. Women are likely to manifest more symptoms than men, with same HIV-loads.

Table 3. Increases in CD4-lymphocytes counts and reductions in viral loads of male and female HIV/AIDS patients, on Antivirt®-treatment

Months	Men		Women	
	CD4	VL	CD4	VL
0	484	1269	502	2056
1	220	2386	283	3057
2	518	991	503	1811
3	702	449	688	892
4	824	250	847	388
5	1009	117	1006	225
6	1587	50	1515	114
7	2012	16	1887	47
8	3697	0	2283	25
9			2548	9
10			2992	0

Legends: CD4 = CD4-lymphocytes counts. VL= Viral loads

Lymphocytosis is normal immune response to viral infections [19] but with HIV, patients suffer lymphopeania, instead. This abnormal response is what made HIV/AIDS incurable. Other viruses also infect cells in organs/tissues that medicines do not reach but when patients are effectively treated, immunity clears infections from such cells. In case of HIV, because it causes immunodeficiency once medicines fail to act on all infected cells, nothing could terminate its infections hence it is said to be in "sanctuary". Restoration of the normal immune response is an additional mechanism by which regimen of MSAMS-*Nanoparticles* and immune stimulants cured the HIV/AIDS-patients. With lymphocytes highly proliferated in treated patients, there would be no hiding place ("sanctuary") for HIV. HIV/AIDS patients tested HIV-negative immediately lymphocytosis (recovery from AIDS) occurred. Therefore, treatment with Nano-medicines and concurrent enhancement of patients' immune responses may be best strategy for termination of HIV infections.

Table 4. Pre-treatment CD4-Lymphocytes counts of HIV/AIDS patients and durations (months) of treatment with Antivirt® before they tested HIV-negative

Samples	CD4 (X)	Treatment-duration (Y)
M_1	628	8
M_2	550	8
M_3	601	8
F_1	789	9
F_2	300	10
F_3	270	10
F_4	750	9
F_5	450	10
F_6	340	10
F_7	290	10

In this clinical trial patients who were confirmed positive for HIV/AIDS became HIV-negative (antigens and antibodies) after treatment with the MSAMS and immune stimulants. Therefore the treatment may have cleared the HIV infection from all their` organs/tissues. If there were still HIV in their "sanctuary cells", the antibody and copies of the RNA-antigen would have persisted.

Mean of pre-treatment CD4 counts of the male-patients was less than that of the female-patients though the two means did not vary significantly. Therefore, significantly higher CD4 counts (3696.67±508.54) in the males, than 2282.86±116.40 of the females, recorded after 8-

months` treatment, suggests that men`s immune systems recovered faster than those of women. That 88.02% of HIV infections was intracellular in males while only 48.69% was so "arrested" in females also suggests better immune responses in males than in females. However, that CD4 counts of the females approximated that of males after additional treatment-duration suggests that the superior immunity of males may be limited to rapid response, only.

In Month-4 of the treatment, CD4 counts of the females (847/ml) was slightly higher than males` (824/ml) and it was only in that month that viral load-reduction rate of the females (56.50%) was better than that of males (44.32%). This suggests that differences in recovery-rates between individual patients or between the sexes may depend on their immune response-rates. Therefore, any management strategy which elicits lymphocytosis earlier, may shorten the treatment-duration. Also, more attention should be paid to enhancing immune responses in female patients.

The patients were on the Antivirt® medication for ten months without noticeable side effects. That means, the regimen is safe. The regimen being so safe may be because AMS is an inactive substance (chemically). It terminates viral infections by a physical effect (adsorption onto viruses and onto virus-infected cells). All that is needed to cure HIV/AIDS may be to continue the medication till lymphocytosis occurs. To confirm that cure for HIV/AIDS has occurred, patients must test HIV-negative (antibody).

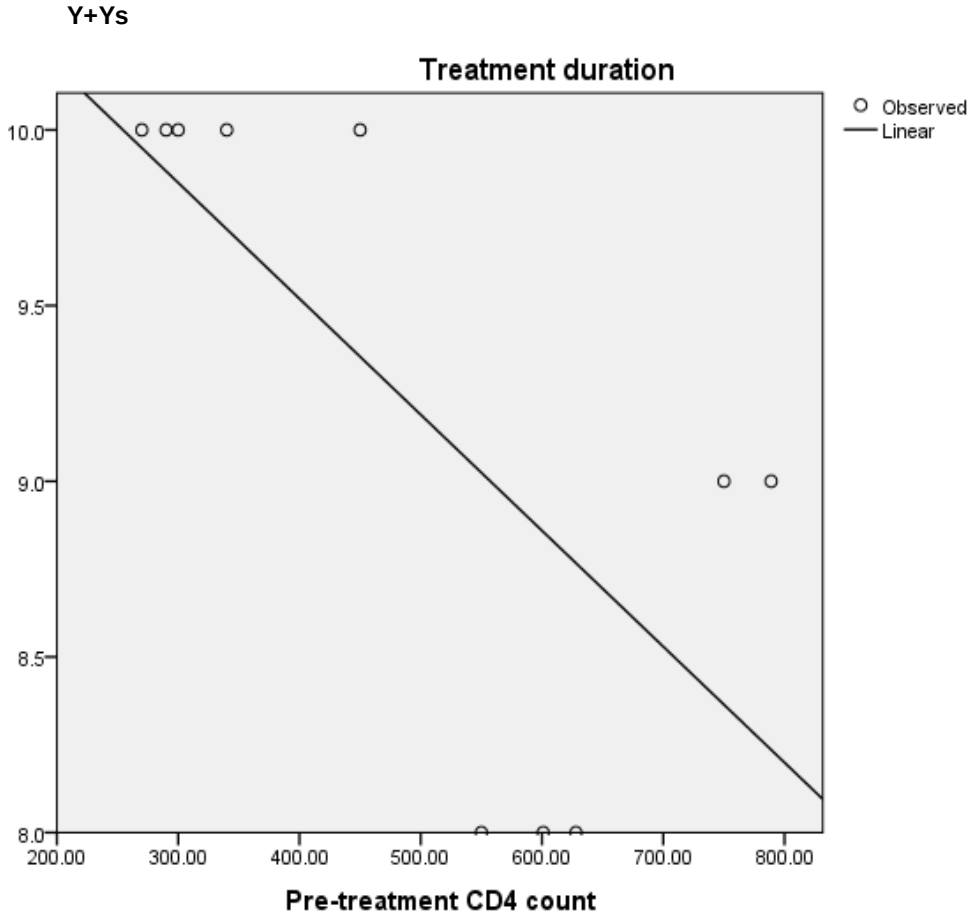

Fig. 1. Relationship between pre-treatment CD4-lymphocytes counts of HIV/AIDS patients and durations (months) of the Antivirt® -treatment before they became HIV-negative

Relationship exists between pre-treatment CD4 counts and treatment durations (Fig. 1). Therefore the equation (Y=10.84 - 0.003X) can be used to estimate treatment-durations for HIV/AIDS patients. Also, existing techniques can not detect copies of RNA, fewer than 3/ml [20]. That makes use of viral loads, alone, to confirm HIV-status of patients, impossible. Combinations of: CD4 counts and viral loads; CD4 counts and presence of antibody; viral loads and presence of antibody, are being used [21]. Patients whose CD4 counts improve to ≥3439.56 can be tested for HIV-antibody, to confirm their status.

4. CONCLUSION

HIV/AIDS patients, treated with **Antivirt®** and immune stimulants became HIV-negative and had their immune responses normalized (CD4 counts ≥ 1500) . Rates of reduction of copies of HIV- RNA in blood of treated patients depended on degree of lymphocytosis. It was also observed that lymphocytes counts improved more rapidly in males than in females. The more rapid improvement in lymphocytes counts may be responsible for the shorter treatment-duration before recovery, recorded in males than in females.

CONSENT

Each patient consented for the clinical trial by writing through his/her physician.

ETHICAL APPROVAL

The clinical trial was conducted in accordance with the Helsinki declaration of 1964, as operational in Nigeria

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. National Agency for Control of AIDS. Nigeria now has second highest HIV/AIDS population in the world. NACA publication; 2013.
2. World Health Organization. Consultation on technical and operational recommendations for scale-up of laboratory services and monitoring HIV antiretroviral therapy in resource-limited settings. WHO Office, Geneva; 2004.
3. World Health Organization. Laboratory Guidelines for Enumerating CD4 T Lymphocytes in the Context of HIV/AIDS. World Health Organization Regional Office for South-East Asia, New Delhi; 2007.
4. Gentile M, Adrian T, Scheidler A, Ewald M, Dianzani F, Pauli G, Gelderblon HR. Determination of the size of HIV using Adenovirus type 2 as an internal length marker. J. Virol. Methods. 1994;48(1):43-52.
5. Vanderbilt Report. Technical Information: "VEEGUM—The versatile ingredient for pharmaceutical formulations. RT. Vanderbilt Company Bulletin No. 91R, 1984. RT. Vanderbilt Company, Inc., Norwalk; 2012.
6. Yokoyama M. Structural mechanisms of immune evasion of HIV 1 gp 120 by genomic computational and experimental science. Uirusu. 2011;61:49-57. Available:http://dx.doi.org/10.2222/jsv.61.49
7. Dennis VP, Lasse K. Students discover method to kill cancer. M. Sc thesis, University of Engineering Finland; 2013.
8. Galindo LA, Cereso P. Compositional technical and safety specification of clay to be used as pharmaceutical and cosmetic products. Journal of Renal Nutrition. 2006; 2:38-40.
9. Ezeibe MCO. The medicinal synthetic Aluminum-Magnesium Silicate (*Nanoparticles*)—Antiviral agent and adjuvant to chemotherapeutics. Federal Republic of Nigeria Patents and Designs Ref No.: NG/P/2012/639; 2014.
10. Murray KR. Harpers biochemistry. McGraw Hill, New York; 2000.
11. Ezeibe MCO, Ngene AA., Kalu IK, Ezeh IO, Mbuko IJ, Ekwuruke JO, Anene I, Amechi B, Olowoniyi P, Ifekwe IF. Assessment of antiretroviral effects of a synthetic aluminum-magnesium silicate. BJMMR. 2014;4:1672-1679.
12. Ezeibe MCO, Ijabo O, Uzopuo C, Okoroafor ON, Eze JI, Mbuko IJ, Sanda ME, Animoke PC, Ngene AA. Effects of Aluminium-Magnesium Silicate on newcastle disease virus and on recovery of infected chicks. 365 International Journal of Biological and Chemical Sciences. 2011;5:825-829. Available:http://dx.doi.org/10.4314/ijbcs.v5i2.72160

13. Ezeibe MCO, Nwaogu IC, Nwaigwe AN, Okoroafor ON, Eze JI, Ngene AA. Aluminum- Magnesium silicate inhibits canine parvovirus and cures infected dogs. Health. 2010;2:1215-1217. Available:http://dx.doi.org/10.4236/health.2010.210179
14. Ezeibe MCO, Mbuko IJ, Okoroafor ON, Okonkwo AC, Animoke PC, Orajaka LJE, Ngene AA. *In vitro* and *in vivo* effects of aluminum-magnesium silicate on infectious bursal disease virus in chikens. Animal Science Reporter. 2009;3:132-137.
15. Ezeibe MCO, Aleeyu D, Ogbonna IJ, Kalu E. Clinical trial of medicinal Synthetic Aluminum-Magnesium Silicate (Antivirt®) on Viral loads and CD4-Lymphocytes counts of HIV/AIDS patients. World Journal of AIDS. 2016;6:37-41. Available:http://dx.doi.org/10.4236/wja.2016.62005
16. Ezeibe MCO, Aleeyu D, Aneke NK, Obarez, TN, Ogbonna IJ, Kalu E. Assessment of antiretroviral efficacy of the Medicinal Synthetic Aluminum-Magnesium Silicate {Al4(SiO4)3 + 3Mg2SiO4 → 2Al2Mg3(SiO4)3}. World Journal of AIDS. 2016;6:74-80. Available:http://dx.doi.org/10.4236/wja.2016.62011
17. Ezeibe MCO, Ogbonna IJ. Enhancing efficacy of antimicrobials with the Medicinal Synthetic Aluminum-Magnesium Silicate, for prevention and treatment of resistant infections. BJMMR. 2015;9(6):1-8.
18. Cristina E, Ivan P, Kevin R. Nanomaterials and nanoparticles: Sources and toxicity. Biointerphases. 2007;2:17-21.
19. Ashwini S, Madhuri T, Philip RA, Ramesh P. A review on peripheral blood CD4-T lymphocyte counts in healthy adult Indians. Indian J. Med. Res. 2010;132(6):667-675.
20. Marck F, Werner H, Alex K, Peter O, Milos O, Ruedi L, Rainer W, Richard WC. Highly sensitive methods for quantitation of Human immunodeficiency virus type 1 RNA from plasma, cells and tissues; 1999. Available:www.jcm.asm.org
21. NAM. Types of viral load tests; 2016. Available:www.aidsmap.com

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