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ORIGINAL ARTICLE

Clinical trial for evaluation of a Human Immunodeficiency Virus nosode in the treatment for Human Immunodeficiency Virus-Infected individuals

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ABSTRACT

Introduction: Identifying the need for strengthening of the immune system, the investigator has developed new Human Immunodeficiency Virus (HIV) nosode and evaluated its effect on HIV positive individuals through a clinical trial.

Methods: Standardized and the scientific method of HIV nosode preparation has been described and documented. Thirty-seven HIV-infected persons were registered for the trial, and ten participants were dropped out from the study, so the effect of HIV nosode 30C and 50C, was concluded on 27 participants under the trial.

Results: Out of 27 participants, 7 (25.93%) showed a sustained reduction in the viral load from 12 to 24 weeks. Similarly 9 participants (33.33%) showed an increase in the CD4+ count by 20% altogether in 12th and 24th week. Significant weight gain was observed at week 12 ($P = 0.0206$). 63% and 55% showed an overall increase in either appetite or weight. The viral load increased from baseline to 24 week through 12 week in which the increase was not statistically significant ($P > 0.05$). 52% (14 of 27) participants have shown either stability or improvement in CD4% at the end of 24 weeks, of which 37% participants have shown improvement (1.54–48.35%) in CD4+ count and 15% had stable CD4+ percentage count until week 24 week. 16 out of 27 participants had a decrease (1.8–46.43%) in CD8 count. None of the adverse events led to discontinuation of study.

Conclusion: The study results revealed improvement in immunological parameters, treatment satisfaction, reported by an increase in weight, relief in symptoms, and an improvement in health status, which opens up possibilities for future studies.

Keywords: Clinical trial, CD4, Homoeopathy, Human Immunodeficiency Virus, Nosode, Potentized, Ultra-dilution, Viral load

INTRODUCTION

Human Immunodeficiency Virus (HIV) infection is characterized by a progressive loss of CD4+ T-cells and massive dysregulation of the immune system,

which ultimately leads to AIDS. HIV pathogenesis is extraordinarily complex and begins its course of destruction during the acute phase of infection, which is characterized by robust viral replication concurrent with rapid infection and depletion of

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mucosal CD4+ T-cells. During the chronic phase of infection, CD4+ T-cells are slowly depleted in lymph nodes, effector tissues and blood, which persists until the majority of CD4+ T-cells are depleted and patients develop opportunistic infections and succumb to AIDS.^[1]

CD8 cell count can be a predictor of disease progress in HIV patients. Initial or serial elevated CD8 count while on Highly Active Antiretroviral Therapy (HAART) or an increase in CD8 count from HAART initiation may be early warnings for future treatment failure. A hyperdynamic or over-stimulated CD8 immune response, reflected by activation of CD8 subsets as well as elevated total CD8 count, may accelerate immune dysfunction and certain disease processes.^[2]

Antiretroviral Therapy (ART) regimes allow immune reconstitution but not normalization of the immune response. Therefore, additional therapeutic approaches need to be developed that include the use of immune-based therapy. Therefore, new innovative remedies having immunological potential to enhance the immune system, Standalone or along with anti-viral treatment, is the need of the hour. Identifying this need, the Investigator has developed homoeopathic preparation called *HIV nosode* and evaluated its effect on HIV-positive humans. He is interested in exploring ways to support immune response to prevent the progression of AIDS, as well as to reduce the number and intensity of opportunistic infections and to improve the overall state of health.

HIV research has grown worldwide and achieved significant success in the development of the antiviral drugs, which has changed Quality of Life for HIV-infected people and increased their life expectancy. However, these drugs do not cure the infection and their prolonged use often provokes significant adverse effects and results in the emergence of drug-resistant strains. Moreover, low level of viruses and latent viral reservoirs persist in HIV-infected participants. Flushing out these reservoirs is a major hurdle that remains to be overcome by anti-HIV therapy.^[3]

Important aspects in the management of HIV participants include

- Prevention of spread of HIV infection
- To slow the rate of multiplication of the virus. This for keeps the immune system of the patient healthy, for a longer period of time. Longer the person's immune system stays healthy the progress toward

the development of Acquired Immune Deficiency Syndrome is delayed

- Preventing, controlling and treating opportunistic infections, catabolic wasting or cachexia, etc.

Hence, it is important to search for an effective, safer, better-tolerated alternative, which is natural.^[4]

Central Council for Research in Homoeopathy, India had conducted a multicenter clinical trial (1989–2005) with 870 evaluable participants using different homoeopathic medicines had shown positive role in managing people with HIV infection.^[5] The placebo controlled randomized study had suggested a possible role of homoeopathic treatment in HIV infection in the symptomatic phase, shown a statistically significant elevation of baseline immune status in persistent generalized lymphadenopathy.^[6]

Nosodes are potentized, and extremely diluted preparations from the disease causing organisms used in Homoeopathy for the treatment of diseases but not restricted to those caused by the source organisms. Nosodes produced from diseased tissues containing *Neisseria gonorrhoea*, *Treponema pallidum*, *Mycobacterium tuberculosis*, Smallpox virus, etc., have been in use in Homoeopathy since 1890.^[7,8] The investigator has developed HIV and Hepatitis C nosodes and also have conducted human studies.^[9]

Extremely diluted and potentized preparations have shown to retain starting material in the form of nanoparticles.^[10] Clinical efficacy of potentized preparations in HIV management has been shown in clinical studies.^[11] Efficacy of homoeopathic medicine has been questioned by some in the past.^[12] The law of similar, the fundamental homoeopathic principle, which states that any substance, which has a capacity to produce symptoms in humans, also has the capacity to relieve similar symptoms, if administered in very small dose.^[13] As the HIV virus produces AIDS and related diseases, it was decided to examine the hypothesis of Homoeopathy through this study of examining the role of the HIV nosode in HIV-infected participants. The investigator has conducted Homoeopathic Pathogenetic Trial (a method to investigate the effect of potentized substance on healthy human volunteers, $N = 22$) of *HIV nosode* (accepted publication) and documented the capacity of the nosode to produce 130 symptoms in healthy volunteers.

Objectives

- To prepare, standardize and evaluate safety of HIV nosode
- Evaluate the treatment of HIV nosode in HIV-infected participants in terms of reduction in viral load
- Improvement of immunological parameter such as CD4 and CD8 count and CD4 percentage, at different time points (12, 24 weeks and 12–24th weeks)
- General health parameters.

METHODS

Method of (HIV) Nosode Preparation

An Institutional Ethics Committee approved the project of HIV nosode preparation as well as the informed consent forms. Blood samples from HIV-infected consented donors (type I and II, one volunteer each) were collected for preparing the nosode. The volunteers were negative for other possible co-infections. Sera from two samples was separated, mixed, and processed for making the source nosode. Standardization of this source nosode with respect to viral count (4153 viral copies by Polymerase Chain Reaction (PCR) method in HIV type 1^[14] (excluding HIV type 2 viral copies as the method for its quantification was (2010) unavailable), protein profile, and pH was done. One part of the source nosode was mixed with 99 parts of vehicle (water for injection or alcohol) and then exposed to rigorous process called potentization giving 10 strokes with standardized potentizer (electro-mechanical devise, impact of stroke calculated) to obtain 1C potency (10^{-2}). One part of 1C was again mixed with 99 parts of vehicle to repeat the process, to arrive to 2C (10^{-4}), and likewise 3C, 4C, ..., 30C (10^{-60}), etc., are prepared. Fifteen steps, a standardized and scientific method of nosode preparation with an example of HIV nosode has been described in detail.^[6] The potencies up to 6C were prepared using water for injection, and above 6C potencies were made using alcohol as vehicle. The extremely diluted (potentized) homeopathic medicines are generally administered in 30C, 200C (or more) potencies.

Standardization of 30C potency and its safety in terms of absence of viral copies by PCR and ultra-electron microscopy was done. The 30C potency was found to be free from HIV virus.

Method of Clinical Trial with HIV Nosode (HIV Nosode was Coded as IMaid)

An exploratory clinical trial was conducted in 36 seropositive participants. Participants were enrolled

in the study as per inclusion and exclusion criteria described in the protocol. CD4 absolute count more than 350 cells/ μ L was one of the inclusion criteria. HIV nosode 30C for first 3 months and 50C for next 3 months were prescribed to the participants. Participants were monitored every 6 weeks during follow-up visits. The dose of six pills (size 30) 3 times a day sublingual was administered to each participant. The documentation such as patient informed consent forms, laboratory investigations at the central laboratory, safety, and ethical measures were taken care of. The participants were followed critically for 6 months, and collected data were analyzed. Participants were monitored for CD profile and viral count at scheduled visits. Participants were examined by HIV AIDS specialist, specific investigations if required were done at central laboratory. Participants whenever required were referred to the counselor at the nongovernmental organization (NGO) for counseling as per the requirement.

Treatment in terms of reduction in HIV viral load compare to initial load (baseline), increase in CD4 count by 20% after 12 weeks or 24 weeks, decrease in CD8 count from baseline after 12 weeks or 24 weeks, change in CD4 %, percentage of participants for sustained reduction in viral load after 12 and 24 weeks of treatment, overall improvement in health (such as weight gain, improved appetite, less opportunistic infections) and health status reported by participant receiving 12 and 24 weeks treatment were evaluated. Treatment of responders (the participant who positively responded to nosode) and non responders was also reported.

Guidelines, Ethics, Compliance and Approvals

The project was reviewed and approved on 16th September 2010, by Institutional Ethics Committee, (Homoeopathy India private limited) constituted as per Indian Council of Medical Research (ICMR) guidelines.^[15] The requirements regarding the obligations of investigators as per 'Guidance on Good Clinical Practice' (GCP) and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Independent Ethics Committee^[16] were met with. The study has been registered (CTRI/2011/12/002228) with the Clinical Trials Registry-India,^[17] set up by the ICMR's National Institute of Medical Statistics.

Patient Population

Inclusion criteria

Patients satisfying all of the following criteria were included in the study:

- HIV (Type I or/and II) seropositive, documented as per WHO guidelines, ≥ 350 CD4 + cells/mm³ at the time of screening
- Who were never on Anti retroviral Therapy (treatment naive patients)
- Who had not received any experimental HIV vaccines
- Male or female between 18 and 65 years of age (inclusive, at the time of signing the informed consent and having an estimated life expectancy of more than 12 months)
- Having viral load of ≥ 500 copies/mL
- Able to receive an optimized regimen
- Free from any serious acute infection or serious medical illness within 14 days prior to study entry
- Ambulatory status, and ability and willingness to give informed consent
- Without actual or suspected allergies to any component of IP
- Female patients of child bearing potential must have a negative pregnancy test prior to IP administration.
- Female patients must agree to use effective birth control methods during the course of the study.

Exclusion criteria

Patients satisfying any of the following criteria were excluded:

- Unable or unwilling to comply with the dosing schedule and protocol evaluations
- Any obvious indications for ART
- Clinical Stage IV (AIDS)
- Having opportunistic infection characteristic of AIDS and clinically suspected tuberculosis who were on or eligible for anti-Koch's therapy
- Clinically suspected and treated cancer
- Psoriasis
- Other critical diseases such as history of seizures, cerebrovascular accident or transient ischemic attacks, renal failure, liver failure, etc
- On injectable and oral corticosteroids
- Terminally ill patients, including AIDS, requiring hospitalization
- On any homeopathic medicine in last 1-month
- Pregnant and/or lactating women.

Statistical Method

Independent agency (contract research organization) carried out data entry, and the data analysis after database was locked. Continuous data were presented

by descriptive statistics N (number), mean, standard deviation, median, minimum and maximum values. Categorical data were presented as frequency (n) and percentage. Comparison of variables representing categorical data were performed using Chi-square or Fisher's exact test. Mean differences of continuous variables from baseline were examined by *t*-test or analysis of variance if more than two subgroups (factor categories) were included. All *P* values were reported based on two-sided significance test, and all the statistical tests were interpreted at 5% level of significance level. Analysis was carried out using Statistical Analysis System program. Efficacy results were on protocol population and safety was on the intention to treat population.

RESULTS

59 participants were screened, 22 were excluded. Many of the participants failed to satisfy the inclusion criteria for CD4 count ≥ 350 CD4+ cells/mm³ and satisfied the exclusion criteria of having clinically suspected tuberculosis who were on or eligible for AKT. 36 participants were enrolled in the study of which 9 did not provide outcome data while 27 participants completed the study. 8 participants were lost to follow-up and one participant voluntarily withdrew consent [Figure 1]. All participants were Asians, with a mean age of 34.39 (standard deviation = 7.98) years, mean weight of 56 kg; 83.33% of the participants in the study were males [Table 1]. All participants were only HIV type I infected. Most of the participants enrolled in this study were from NGOs and drug-addiction centers. Few participants were shifted to another NGO and hence lost to follow-up. However,

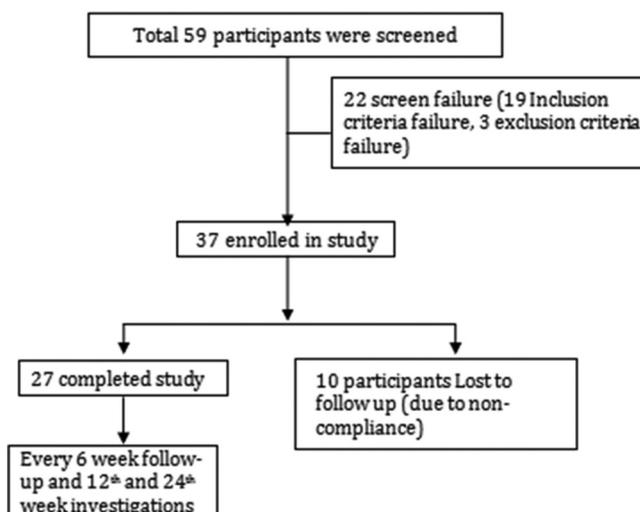


Figure 1: Participant's flow chart

the telephonic conversation with NGO confirmed the safety of such participants. Of 27 participants, seven responders (25.93%) showed a sustained reduction in the viral load from 12 to 24 weeks [Table 2].

Overall the viral load is increased from baseline to week 24 through week 12 in which the increase was not statistically significant ($P > 0.05$) [Table 3].

18.52% (5 of 27) participants showed an increase in CD4 count by 20% at 12th week with 30C potency of the nosode, not sustainable, as count of these participants dropped at 24th week. With 50C potency, increase in CD4 count by 20% was observed in 14.81% participants [Table 4].

Overall, it was observed that 37% (10 of 27) participants have shown improvement (1.54 - 48.35%) in CD4% count and 15% (4 of 27) participants had a stable CD4%

Table 1: Demographics

Parameter	Demography (n=27)
Gender, n (%)	
Male	22 (81.48)
Female	5 (18.52)
Race, n (%)	
Asian	27 (100.0)
Age, (years)	
n	27
Mean (SD)	34.59 (8.01)
Median	34
(Minimum, maximum)	(22, 57)
Weight, (kg)	
n	27
Mean (SD)	56.70 (11.09)
Median	56
(Minimum, maximum)	(41,78)
Height, (cm)	
n	27
Mean (SD)	164.07 (6.51)
Median	164
(Minimum, maximum)	(149,180)

SAS Program: Table 14.1.4.sas. a: The denominator for percentages is the total number of patients in the safety population. SAS: Statistical analysis system; SD: Standard deviation

Table 2: Percentage of patients for sustained reduction in viral load after 12 and 24 weeks of treatment

	Responders	Nonresponders
Week 12	7 (25.93)	4 (14.81)
Week 24	3 (11.11)	13 (48.15)
P	1.0000	

SAS program: Table 14.3.5.1 sas/analysis dataset: Viral load.sas7bdat. Note: Analysis is done on non-missing data. P value was obtained using McNemar's test. SAS: Statistical analysis system

count until visit 5. Thus, 52% (14 of 27) participants have shown either stability or improvement in CD4% at the end of 24 weeks. [Table 5].

In this study, 16 out of 27 participants had a decrease (1.8–46.43%) in CD8 count and eleven participants showed elevated CD8 count (not statistically significant), such an over-stimulation of CD8 response and an elevated cell count was clinically associated with accelerated HIV disease progression [Table 6].

No statistically significant change was observed in the CD8 count and CD4 percentage count from baseline to week 12 and week 24.

Weight gain was seen in participants at both 12 weeks and 24 weeks; the mean increase being

Table 3: Reduction in viral load (copies/ml) compared to baseline (PP population)

Parameter	Descriptive analysis	(n=27)
Baseline	n	27
	Mean (SD)	120,494.6 (132,358)
	Median	76,945
	Minimum, maximum	2307, 539,505
Week 12	n	26
	Mean (SD)	170,705.1 (293,216)
	Median	139,237
	Minimum, maximum	212, 1,530,071
Change from baseline to week 12	n	26
	Mean (SD)	-53,681.1 (241,647)
	Median	-10076
	Minimum, maximum	-1,160,400, 286,533
	P ^[a]	0.2681
Week 24	n	27
	Mean (SD)	240,239.6 (443,662)
	Median	124,875
	Minimum, maximum	354, 2,317,364
Change from baseline to week 24	n	27
	Mean (SD)	-119,745.0 (382,193)
	Median	-5127
	Minimum, maximum	-1,947,693, 88,811
	P ^[a]	0.11

SAS Program: Table 14.3.1.1.sas/analysis dataset: Viral load.sas7bdat. a: n is the total number of patients in PP. ^[a]P value was calculated using paired t-test at 5% level of significance. PP: Protocol population; SAS: Statistical Analysis System; SD: Standard deviation

Table 4: Proportion of participants with an increase in CD4+count (/mm³) by 20% from baseline to week 12 and week 24

Increase in CD4 count (cells/mm ³) by 20%	n=27	Percentage
Week 12	5	18.52
Week 24	4	14.81

2.02 and 1.67 kg, respectively. Significant weight gain was observed at week 12 ($P = 0.0206$) [Table 7].

A significant proportion of participants, 63% and 55% showed overall improvement in either appetite, or weight gain or reduction in opportunistic infections at week 12 and week 24, respectively as per individual patient narratives for opportunistic infections [Table 8 and Table 9].

Patient-wise short narratives were prepared, and the Investigator and HIV consultant opined clinically on the general health (weakness, feeling of well-being and treatment satisfaction) and improvement in terms of relief from symptoms and recurrence of infection. Sixty percent of the patients had improved in terms of the general condition, relief from symptoms and recurrence of infection.

3 (11.11%) out of 27 participants had infection at baseline. The number of participants having infections increased from 3 to 13 (of 27) at week twenty-four. Upper respiratory tract infection (5 participants) was the most commonly observed infection. One case of lower respiratory tract infection was observed. This may indicate the disease progression. Increase in fatigue from 0 at baseline to 4 at the end of 24th week was observed.

22 (66%) of 36 participants experienced Adverse Events (AEs). None of the AEs was serious. Most of the AEs (72.73%) experienced by the participants belonged to the system organ class of infections and infestations, followed by 'respiratory, thoracic and mediastinal disorders' (40.91%) and 'general disorders and administration site conditions' (40.91%). The most common AEs reported were URTI (40.91%) and nasopharyngitis (40.91%), followed by pyrexia (31.82%). None of AEs and serious adverse events was suspected to be caused due to the study drug. All the AEs reported during the study were mild in intensity.

DISCUSSION

The number of people receiving ART has increased considerably in recent years, with a notable increase of 900,000 in the number of people receiving ART since the end of 2011, until November 2012.^[18] Antiretroviral therapies, focusing on reduction in viral load entail treatment with "drug cocktails". Currently, integrase inhibitors and entry inhibitors are new classes of anti-retroviral being investigated

Table 5: Percentage change in CD4% count as compared to baseline

Effect on CD4 percentage count	n=27	Percentage
Improvement in CD4% count	10	37
Stable CD4% count	4	15

Table 6: Change in CD8 count from baseline to week 12 and week 24

Change in CD8 count	Descriptive analysis	(n=27)
Baseline visit	Mean (SD)	1498.0 (764.49)
	Median	1316.5
	Minimum, maximum	589, 3468
Week 12	Mean (SD)	1513.1 (781.81)
	Median	1318
	Minimum, maximum	35, 3803
Change from screening visit to week 12	Mean (SD)	-4.23 (414.16)
	Median	102
	Minimum, maximum	-874.0, 723.00
	P ^[a]	0.9589
Week 24	Mean (SD)	1361.7 (657.31)
	Median	1205
	Minimum, maximum	425, 3242
Change from screening visit to week 24	Mean (SD)	-122.3 (380.84)
	Median	-114
	Minimum, maximum	-1399, 481.00
	P ^[a]	0.1139

SAS Program: Table 14.3.3.1.sas P. ^[a]P value was calculated using paired t-test at 5% level of significance. Increase in CD8 count from baseline to week 12 and week 24 was calculated by the formula at each visit: Postbaseline count-baseline. SAS: Statistical Analysis System; SD: Standard deviation

Table 7: Weight gain

Weight gain (kg)	Descriptive analysis	(n=27)
Mean (SD)	56.70 (11.09)	-
Median	56	-
(Minimum, maximum)	(41, 78)	-
Change from baseline to week 12	Median	1.00
	Mean (SD)	2.02 (4.25)
	Minimum, maximum	-4.00, 14.00
	P value	0.0206
Change from baseline to week 24	Median	1.00
	Mean (SD)	1.67 (5.08)
	Minimum, maximum	-6.00, 15.00
	P value	0.0999

SAS Program: Table 14.3.6.1.sas analysis P. ^[a]P value was calculated using paired t-test at 5% level of significance. SAS: Statistical Analysis System; SD: Standard deviation

Table 8: Overall improvement in health

Duration	n	Overall improvement in health (%)	95% CI (lower limit, upper limit) (%)
12 weeks	27	17 (62.96)	(42.37, 80.60)
24 weeks	27	15 (55.56)	(35.33, 74.52)

SAS Program: Table 14.3.7.1.sas/analysis. a: n is the total number of patients in PP population P. ^[a]P value was calculated using Binomial test at 5% level of significance. SAS: Statistical Analysis System

Table 9: Proportion of patients with the overall improvement in health by satisfying all of the criteria (n=27)

	URTI (%)	LRTI (%)	GI (%)	Oropharyngeal candidiasis (%)	Fatigue (%)	Others (%)
Baseline						
No	27 (100.00)	27 (100.00)	25 (92.59)	26 (96.30)	27 (100.00)	2 (100.00)
Yes	0	0	2 (7.41)	1 (3.70)	0	0
Week 12						
No	21 (77.78)	27 (100.00)	27 (100.00)	26 (96.30)	24 (88.89)	2 (50.00)
Yes	6 (22.22)	0	0	1 (3.70)	3 (11.11)	2 (50.00)
Week 24						
No	22 (81.48)	26 (96.30)	25 (92.59)	27 (100.00)	23 (85.19)	1 (50.00)
Yes	5 (18.52)	1 (3.70)	2 (7.41)	0	4 (14.81)	1 (50.00)

SAS Program: Table 14.3.9.1.sas/analysis. URTI: Upper respiratory tract infection; LRTI: Lower respiratory tract Infection; GI: Gingival index; SAS: Statistical Analysis System

in clinical trials.^[19] Research has also been pursued in the development of immunomodulators in the prevention or treatment of HIV infection. Alternative systems of medicine have explored the possibility of identifying therapies for HIV.^[20]

This was an exploratory study to evaluate a new homeopathic medicine, HIV nosode, for the treatment for HIV. This study was conducted to examine the role of the HIV nosode in HIV-infected participants and to explore its efficacy and safety. Since this nosode was sourced from biological material, its safe use in human was documented carefully by testing for viral copies and genetic material. Inventor had also tested this nosode on healthy volunteers through a separate study, the Homeopathy pathogenetic trial, and documented its safe use.

An overview of the results and the individual patient narratives reveal that most participants in different stages of the disease, experienced treatment satisfaction as reported by an increase in weight, relief in symptoms and improvement in health status, during their scheduled visits. The progression of HIV illness depends on the increase of viral load and depletion of CD4+ count. The efficacy of the HIV nosode may be evaluated on enhancement of CD4+ count and reduction in viral replication. The participants who responded positively to the nosode therapy had shown 18.52% increase in CD4 at 12th week with 30C potency of the nosode, not sustainable, as the count of these participants dropped at 24th week. With 50C potency, increase in CD4 count by 20% in 14.81% patients, further follow-up of these patients not available to observe whether count sustained or not. In the responder group, 25.93% participants have shown a sustained reduction in the viral load from week 12 to 24.

Overall the viral load increased from baseline to week 24; though the increase was not statistically significant ($P > 0.05$).

A mixed response was observed at week 24, wherein some participants improved and some had a relapse in their symptoms. Elevated CD8 count in eleven participants may show the HIV disease progression.^[21] The limitation of the study was lack of the control group and hence it is difficult to arrive at the conclusion whether this fall in CD4 is related to the treatment or the natural course of the disease.

This also could point to the possibility that 30C potency gave a better result than 50C potency, as a shift from 30C to 50C led to weakening in results after week 12. Other limitations of the study were 25% dropout rate, small sample size, lack of the placebo arm and short duration. It may be noted that placebo control study has not been possible for a disease like HIV due to ethical reasons. A follow-up study to evaluate either the continuation of the lower potency (30C) for a longer duration or therapy for a shorter duration, and control group (randomized control trial) in a greater number of participants is warranted.

Author has conducted clinical trial in the participants having HIV infection to examine the fundamental Law of Similars used in Homeopathy. The homeopathic pathogenetic trial, a placebo-controlled study on healthy human volunteers conducted by the author has demonstrated effects of ultra-diluted, potentized HIV nosode in 30C potency by producing a set of symptoms comparable with those due to the HIV virus.

The mechanism of the action of the nosodes is not

yet understood. The research may be supported by further study to examine if the action of the nosode as immunomodulator or immunostimulatory. It must be noted that this study is one of its kind involving homeopathic nosodes, which are vaccine like preparations sourced from organisms. The systematic effort has been made to evaluate its effect in HIV-inflicted individuals. The study may be considered a beginning of a series of many experiments with (a) different organisms and nosodes (b) evaluation of various biological markers (c) use of nosodes as adjuvant therapy (d) using nosodes along with constitutional homeopathic medicine.

Clinically, improvement in terms of general condition of patient and improvement in CD4 count may help prolong the need for ART treatment; however, more clinical trials in a large number of participants with participants having homogeneous immune status are obligatory.

CONCLUSION

The most notable features of this study include results such as 25.93% participants showed reduction in viral load, 33.33% participants showed an increase in the CD4+ count by 20%, significant weight gain ($P = 0.0206$), 37% participants have shown improvement in CD4% count and 15% participants had a stable CD4%, and overall improvement in health status. The study revealed improvement in immunological parameters, treatment satisfaction, reported by an increase in weight, relief in symptoms, and improvement in health status. Taking into consideration the results of this study, homeopathic therapy in the future can be explored as adjuvant or stand-alone, which opens up possibilities for future studies.

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REFERENCES

1. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2886291/>. [Last accessed on 2013 Mar 01].
2. Krantz EM, Hullsiek KH, Okulicz JF, Weintrob AC, Agan BK, Crum-Cianflone NF, *et al*. Elevated CD8 counts during HAART are

associated with HIV virologic treatment failure. *J Acquir Immune Defic Syndr* 2011;57:396-403.

3. Hwijin K, Alan SP. Viral and latent reservoir resistance in HIV-1-infected participants on therapy. *PLoS Comput Biol* 2006;2:e135.
4. Available from: http://www.manbir-online.com/std/hiv_3.htm. [Last accessed on 2013 Mar 01].
5. Mishra N, Prasad P, Bhuvaneshwari S, Singh V, Muraleedharan KC, Dey S, *et al*. HIV infection. *Clinical Research Studies Series 1*, New Delhi: CCRH 2008;1:67-82.
6. Rastogi DP, Singh V, Singh VP, Dey SK, Rao K. Double blind placebo controlled clinical trial of homeopathic medicines in HIV infection. *Br Homoeopath J* 1998;87:86-8.
7. Allen TF. *Encyclopedia of Pure Materia Medica*. Vol. 10. New Delhi: B. Jain Publishers; 1810.
8. Hering C. *The Guiding Symptoms of Our Materia Medica*. Reprint ed., Vol. 10. New Delhi: B. Jain Publishers; 1989. p. 211, 350.
9. Shah R. Hepatitis C Nosode: The preparation and homeopathic pathogenetic trial. *Homeopathy* 2013;102:207-14.
10. Chikramane PS, Suresh AK, Bellare JR, Kane SG. Extreme homeopathic dilutions retain starting materials: A nanoparticulate perspective. *Homeopathy* 2010;99:231-42.
11. Muraleedharan KC, Dey S, Prasad P, Siddiqui VA, Dixit R, Singh V, *et al*. Effectiveness of homeopathic medicines in HIV patients – A clinical trial. *Indian J Res Homoeopath* 2010;4:29-35.
12. Shang A, Huwiler-Müntener K, Nartey L, Jüni P, Dörig S, Sterne JA, *et al*. Are the clinical effects of homeopathy placebo effects? Comparative study of placebo-controlled trials of homeopathy and allopathy. *Lancet* 2005;366:726-32.
13. Hahnemann S. *Organon of Medicine*. 6th ed. New Delhi: Jain Publishers; 1981. p. 109-10.
14. Shah R. Scientific method of preparing homeopathic nosodes. *Indian J Res Homoeopath* 2014;8:166-74. Available from: <http://www.ijrh.org/text.asp?2014/8/3/166/141740>. [Last accessed on 2014 Oct 21].
15. Indian Council of Medical Research. *Ethical Guidelines for Biomedical Research on Human Participants*. New Delhi: Indian Council of Medical Research; 2006.
16. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice, E6 (R1). June 10, 1996.
17. Available from: <http://www.ctri.nic.in> [Last registered on 2011 Dec 14].
18. Global Fund Support Extends Antiretroviral Treatment to 4.2 Million People. Geneva; 2012. Available from: http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-29_Global_Fund_support_extends_antiretroviral_treatment_to_4.2_million_people/. [Last accessed on 2013 Mar 01].
19. Tebas P. Cutting – Edge Issues in HIV Medicine (Symposium). Available from: <http://www.thebody.com/content/art31916.html?nxtprv>. [Last updated on 2001 Oct 19; Last cited on 2013 Mar 02; Last accessed on 2013 Aug 10].
20. Arjanova OV, Prihoda ND, Yurchenko LV, Sokolenko NI, Vihrova LA. Impact of adjunct immunotherapy with multi-herbal supplement Dzherelo (Immunoxel) on treatment outcomes in end-stage TB/HIV participants. *J Antivir Antiretrovir* 2009;1:86-8.

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मानव प्रतिरक्षाहीनता विषाणु (एचआईवी) संक्रमित सहभागियों की चिकित्सा में एक एचआईवी नोसोड के मूल्यांकन हेतु लाक्षणिक परीक्षा

संस्करण 3.0 तिथि 10 मार्च 2015

सार

परिचय

प्रतिरक्षा प्रणाली को सशक्त करने की आवश्यकता को पहचानते हुए अन्वेषक ने नया एचआईवी नोसोड विकसित किया है तथा प्रभाव लाक्षणिक परीक्षा द्वारा एचआईवी धनात्मक व्यक्तियों पर इसके प्रभाव का मूल्यांकन किया है।

विधि

एचआईवी नोसोड विरचन की मानकीकृत व वैज्ञानिक विधि को वर्णन कर प्रलेखित कर दिया गया है। परीक्षा हेतु सैंतीस एचआईवी संक्रमित व्यक्तियों का पंजीकरण हुआ परंतु दस सहभागियों को अध्ययन से हटा दिया गया, अतः परीक्षा के अंतर्गत सत्ताईस सहभागियों पर एचआईवी नोसोड 30c तथा 50c के प्रभाव के निष्कर्ष निकाले गए।

परिणाम

सात सहभागियों (25.93%) ने 12वें सप्ताह में और चार सहभागियों (14.81%) ने 24वें सप्ताह में विषाणु भार में सतत कमी दर्शाई। इसी प्रकार 9 सहभागियों (33.33%) ने CD4+ गणन में 12वें तथा 24वें सप्ताह में कुल मिलाकर 20% वृद्धि दर्शाई। बारहवें सप्ताह ($p = 0.0206$) में वजन में काफी वृद्धि देखने को मिली। तिरसठ प्रतिशत और 55% ने क्षुधा या वजन में से किसी न किसी में वृद्धि दर्शाई। विषाणु भार चौबीसवें सप्ताह में आधाररेखा से ऊपर चला गया जबकि बारहवें सप्ताह में सांख्यिकीय दृष्टि से सार्थक वृद्धि ($p > 0.05$) नहीं हुई थी। सैंतीस प्रतिशत सहभागियों ने CD4+ गणन में सुधार (1.54-48.35%) दर्शाया है और 15% का CD4+ प्रतिशत गणन चौबीसवें सप्ताह तक स्थिर रहा। सत्ताईस में से सोलह सहभागियों के CD8 गणन में कमी (1.8- 46.43 %) आई। किसी भी AE के चलते अध्ययन बंद नहीं हुआ।

निष्कर्ष

अध्ययन परिणामों ने प्रतिरक्षा प्राचलों में सुधार व चिकित्सा संतुष्टि दर्शाई। ऐसा हम वजन में वृद्धि, रोग के लक्षणों से राहत तथा स्वास्थ्य की दशा में सुधार से देख सकते हैं, जिससे आगे भविष्य में और अध्ययनों की संभावनाओं के द्वार खुलते हैं।

मुख्य शब्द

एचआईवी, नोसोड, लाक्षणिक परीक्षा, अति-तनूकरण, शक्तिमानकृत, होम्योपैथी, CD4, विषाणु भार

