# A Double Blind Placebo Controlled Study:

## Homoeopathy in HIV Infection

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**ABSTRACT OBJECTIVE:** This study was aimed to evaluate the immuno-modulator role of homoeopathic remedies in HIV infection.

**METHODOLOGY:** A randomized double blind clinical trial was conducted to compare the effect of homoeopathic remedies with placebo, on $CD4^{+ve}$ T-lymphocytes in HIV infected individuals, conforming to CDC stage II & III. 100 $HIV^{+ve}$ individuals between 18 and 50 years (71% males) were included in the study. 50 cases conformed to CDC stage II - Asymptomatic HIV infection, and other 50 cases to CDC stage III - PGL. Cases were stratified according to their clinical status and $CD4^{+ve}$ Lymphocyte counts. The randomization charts were prepared much before the start

of the trial by randomly assigning placebo and verum codes to different registration numbers from 1 to 50. A single individualized homoeopathic remedy was prescribed in each case and was followed up at a periodic interval of 15 days to one month. A six months study was performed for each registered case. Assessment of progress was made by evaluation of $CD4^{+ve}$ Lymphocyte counts, which was decided as the main out come measure of the study; the results were compared with the base line immune status.

**Results:** In the strata of PGL, a statistically significant difference was observed in $CD4^{+ve}$ T-Lymphocyte counts between pre and post trial levels in verum group ($p < 0.01$). In the placebo group a similar comparison yielded non-significant results. ($p = 0.91$). Analysis of change in the pre & post trial counts of $CD4^{+ve}$ cells was also significant for the verum group ($p=0.04$).

In Asymptomatic HIV infection, differences in absolute $CD4^{+ve}$ Lymphocyte counts between pre and post trial levels were not significant. Analysis of changes in pre & post trial CD4 levels of placebo and verum groups for combined strata of Asymptomatic and PGL groups was also not significant.

**Conclusion:** The study suggests a promising role of homoeopathic treatment in HIV infection in symptomatic phase, as evidenced by a statistically significant elevation of base line immune status in persistent generalized lymphadenopathy.

Key Words: Immuno-modulator, CD4 Lymphocytes

Abbreviations: HIV - Human Immuno-deficiency Virus; PGL - Persistent Generalized Lymphadenopathy; CDC - Centre for Disease Control, Atlanta, USA.

Double blind placebo controlled trials are uncommon in Homoeopathy, due to inherent problems in the methodology of treatment, ie individualization procedure, treatment by multiple remedial agents for a single clinical diagnosis, etc. However, small group studies have been conducted on clinical problems like Acute childhood diarrhoea[1], Influenza[2], Allergic Rhinitis[3], Fibrositis[4], Osteo Arthritis[5]. These trials with the exception of the last named, have suggested a significant positive role of Homoeopathic treatment when compared to the placebo. A meta-analysis of placebo-controlled trials in Homoeopathy was conducted[6]. The results of this analysis are not compatible with the hypothesis that clinical effects of Homoeopathy are completely due to placebo. However, the investigators could not find enough evidence of efficacy of homoeopathy for any clinical condition.

Placebo controlled trials of therapy to inhibit progress of HIV associated disease have met considerable resistance, as the patients have been reluctant to accept the risk of receiving a placebo. In this context, it is worthwhile to consider that in the face of HIV disease, the smallest chance of benefit is perceived as better than no benefit. Additionally, enough measures have been included in our trial protocol, so that patients not benefited by the therapy can be subjected to active therapeutic intervention in such an eventuality and not allowed to deteriorate further. Placebo controlled trial with Homoeopathic medicines was not conducted in Human Immuno-deficiency Virus (HIV) infection, prior to our study. A preliminary report of our study is already published[7]. The present article deals with interpretation of the results of the study with the help of a statistical analysis.

The primary target of HIV is the lymphocytes, which express CD4 protein on their surface, and the virus attaches to the lymphocyte, using this protein. These $CD4^{+ve}$ T-Lymphocytes are preferentially infected and killed by the HIV as the infection progresses, depleting their numbers and enhancing the risk of opportunistic infections. Furthermore, it is known that the extent of CD4 depletion is strongly associated with the risk of clinical progression and survival. Although any one individual may be an exception, for populations of HIV infected persons, studies have shown an unequivocal association between low levels of $CD4^{+}$ cells and measurable deleterious events that are AIDS defining phenomena and by extrapolation, predict survival. The

absolute CD4$^{+ve}$ T-Lymphocytes at any given point of time, is the best available cellular predictor of HIV progression, and is the most important factor of survival, regardless of how the individual achieved that level. Relatively small shifts in the numbers of CD4$^{+ve}$ cells can be very important if they bring an individual's cell count into a better prognostic category. A stable CD4 level indicates HIV non-progression and therefore a halt in the decline in the number of CD4$^{+ve}$ cells is viewed as meaningful[8]. Therefore CD4$^{+ve}$ T-Lymphocytes are often used as surrogate markers in clinical trials. Initial trials using CD4 cells as surrogate immunological markers would establish that a therapy is potentially effective[9]. This should then pave way for larger multi-parametric studies involving immunological and virological markers.

Few studies in the past have indicated beneficial effect of homoeopathic treatment in HIV infection[10,11]. The Central Council for Research in Homoeopathy took up open pilot studies and followed a number of HIV$^{+ve}$ cases in different CDC stages and observed improvement both in terms of clinical manifestations and immunological status.[12,13,14,15] However, if a placebo controlled trial by homoeopathic medicines was shown to be influencing the CD4$^{+ve}$ T-Lymphocytes in a beneficial manner, it would confirm the observations made in earlier studies.

## METHODS

A randomized double blind placebo controlled clinical trial of homoeopathic treatment in HIV infection was conducted by C C R H at Regional Research Institute for Homoeopathy, Mumbai, between 22nd July 1995 and 8th February 1997.

The trial was conducted by studying the subjects under two different strata. The first strata comprising of Asymptomatic HIV$^{+ve}$ cases defined by absence of clinical signs and symptoms that correspond to symptomatic HIV disease, viz. chronic recurrent fever, chronic recurrent diarrhoea, progressive neurasthenia/weakness, weight loss, generalized lymphadenopathy, minor or major opportunistic infections, etc. and reasonably good number of CD4$^{+ve}$ Lymphocytes that otherwise classifies the case under symptomatic HIV disease/ AIDS. The second strata comprised of HIV$^{+ve}$ cases that belonged to CDC stage III, Persistent Generalized Lymphadenopathy (defined as enlargement of lymph nodes having a size of >1cm. in diameter, in more than two extra inguinal sites and of > three months duration), with good number of CD4$^{+ve}$ Lymphocytes. 50 cases were registered in each strata. The strata were dealt separately by two co-investigators in patient interview, counselling, history taking, remedy selection, follow-up review and periodical analysis. The randomization, blinding of the subjects and medicine dispensing was handled by a co-coordinator separately in absolute confidentiality. The randomization charts were prepared much before the start of the trial by randomly assigning placebo and verum codes to different registration numbers from 1 to 50. The cases were registered at different points of time during the study in the order they have reported to the institute's OPD, and was assigned a registration code as per the pre-coded randomization chart, thus randomly received either placebo or medicine.

Subjects between 18 and 50 years of age (males=71%) who have shown a positive antibody reaction to HIV1 or HIV2 or both confirmed by repeat Elisa and/or Western blot were inducted into the trial (99% HIV-1 infection). Subjects having past history of convulsions or cardiac disease and currently requiring medication for control, those having taken AZT in the immediately preceding four weeks and pregnant and lactating women formed the exclusion criteria and were not considered for the trial. Any subject with poor compliance and follow up less than three months, having taken any other therapy, who have developed any life threatening condition or adverse effects of the therapy which required active therapeutic intervention, and women who have conceived subsequent to registration were considered as lost to follow-up and were not considered for final analysis.

Every case was subjected to pre-entry investigations

as below.

ELISA FOR HIV ANTIBODIES WAS PERFORMED BY :

(1) ImmunoComb®, HIV 1 & 2 Bispot, PBS Orgenics, France- A qualitative and differential detection of HIV-1 & HIV-2 IgG antibodies by Solid phase Enzyme Immunoassay (EIA). (Sensitivity: 100%; Specificity: 98.4%); Batch #: 950027 (Exp.27/08/1996) ; 960205 (Exp.: 25/01/1997)

(2) HIV-SPOT, Diagnostic Biotechnology, Singapore - A rapid qualitative test for the detection of HIV1 & 2 Antibodies. (Sensitivity: 98.8%; Specificity: 100%); Batch # : 5LD105 (Exp. 2/11/1996), 6HG104 (Exp. 19/7/1997).

(3) The institute did not posses facilities for Western Blot testing, but the result of a subject who undertook this test in any private laboratory, was taken into cognizance.

- Vacutainer® brand (Becton-Dickinson) Blood collection tubes were used throughout the study for collection of blood samples, sera, and whole blood, etc. The sera were preserved for possible future analysis.
- Routine Haematological investigations performed using QBCII Centrifugal Haematology System (Becton-Dickinson) and QBC Venous & Capillary Blood Tubes (Becton-Dickinson).
- ESR tested using Monovette® (Starstedt, Germany) brand of Blood Collection system.
- VDRL was tested using TrepoStat® - Reagen Protein Reaction (RPR) method.
- A Delayed hypersensitivity reaction was obtained by Montoux skin test which was performed with Tuberculin PPD Solution (10 TU), Span Diagnostics, India.
- Immunocytometry tests (CD4/CD8/CD3) were conducted with FACSCount™ System (Becton-Dickinson) and FACSCount™ system reagents and controls. The instrument employs direct two-colour immunofloresecence for enumerating absolute lymphocytes(CD3' cells), and its subsets T-helper Lymphocytes (CD3'CD4') and T-Suppressor Lymphocytes (CD3'CD8'). The system has a built in quality control which prevents erroneous results. The system is fully automated, run by a FACSCount system software and requires no user intervention while running the samples. The enumeration of absolute lymphocytes is direct method and does not require an external haematology instrument.
  Reagent Lot Batch # 50012121 (Exp. 13/10/1995); 50042121 (Exp. 5/2/1996); 60012121 (Exp. 15/4/1997); Control Lot Batch #: 49071721(Exp.13/11/1995); 59011721 (Exp.5/2/1996) ; 59051721 (Exp. 20/6/1997).
- Fluctuations are known to occur in total lymphocyte counts with diurnal cycles[16] . This has been avoided by consistently collecting the haematological samples during the forenoon of the sample collection day from 9am to 11 am, throughout the study period. All samples were processed on the same day of collection to avoid sample instability which may affect the results.
- A routine ECG and chest X-ray taken to rule out any underlying cardiac or chest disease.

Subjects fulfilling the inclusion criteria were inducted into the trial after obtaining an informed consent. Appropriate counselling was provided by the medico social worker and the treating co-investigator as well. A thorough homoeopathic case was taken and the details were entered in a standard data recording proforma. Processing and analysis of symptoms were done using a computerized homoeopathic software - HOMPATH©. Kent, Boenninghausen and Synthetic Repertories were consulted for analysis of symptoms and arriving at the homoeopathic remedy. A range of homoeopathic potencies were used from 6x to LM scale, as per the requirement and analysis by the co-investigator.

After initiation of the treatment, the routine haematological investigations were carried out during follow up, at an interval of one month and immunological and serological investigations at three months.

During every follow-up a pre-defined check list was used to assess the clinical status and response to the treatment. The observations were entered in the standard data recording proforma. The checklist was prepared so as to ensure that the co-investigator inquires into the subject's normal biological functioning like appetite, stool, urine and sleep and appearance of any clinical event attributable to HIV infection. Body weight was recorded on every visit using a standard personal weighing scale. The indicated homoeopathic remedy was prescribed during each follow-up by the co-investigator, which is either continuation of previous remedy in the same potency or higher scale. Any acute complaint arising during the follow-up was prescribed the indicated remedy as the prevailing symptomatology suggested. However, the subjects under control group received placebo and those under active group received the prescribed homoeopathic remedy. (*The protocol guidelines provided for withdrawal of the subject from the study in case of emergent measures to safeguard his health interests.*) After completion of six months study all investigations were repeated

and the final assessment was done in relation to clinical status, haematological and immunological status.

Statistical procedures were performed using SPSS ver 3.0 and Microsoft* Excel ver 7.0 Analysis toolpak. The analysis was independently done at Institute of Research in Reproduction, Parel, (ICMR) Bombay and also at the institute where the trial was conducted, and the results were cross checked and confirmed.

Comparison of mean difference at the beginning and end of the trial between placebo and verum groups was made by two-tailed unpaired t-test (parametric) to arrive at the accurate means and standard deviations. Mann-Whitney-U test (Non-parametric) was considered, to obtain the p value, due to high variances in haematological and immunological test values.

The outcome measures were assessed by observing the mean differences in pre and post trial levels of haematological and immunological status, within placebo and verum groups separately. Exact means were arrived by paired t-test (parametric) and Wilcoxon matched pairs signed rank test (non-parametric) was used to test significance level.

Though the CD4' and CD8' T-Lymphocyte counts were considered as the main outcome measure, other quantifiable haematological parameters were also subjected for the analysis and presented in the tables.

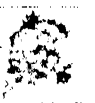
## RESULTS

In each strata, twenty-five cases were assigned to placebo group and an equal number to the verum group. In asymptomatic strata two cases under placebo group left the treatment in the middle. Under the verum group one woman who was detected as ante-natal case subsequent to the registration was dropped out of the study. Five other cases, with poor follow-up compliance were also dropped out and not considered for analysis. A total eight out of the fifty cases (16%) were dropped out in asymptomatic strata (Placebo group 2 cases & Verum group 6 cases).

Similarly, in PGL strata under placebo group one subject was withdrawn from the study owing to the progression of disease which required active therapeutic intervention. The unblinding of the subject was however done at the conclusion of trial period. Six other cases were also dropped out due to poor follow-up and failing to maintain the required length of study as per protocols. Under the verum group one woman who conceived during the follow-up period was dropped from the study. Two cases underwent other therapy during the follow-up and hence were not considered for analysis. Two subjects were treated as lost to follow-up due to poor compliance. Twelve of fifty (24%) cases have formed the dropouts in PGL strata. (Placebo group 7 cases & Verum group 5 cases). All dropouts were marked out before final analysis and unblinding the codes. A spurious way of looking at the results was thus avoided. The details of drop out of cases is given in Table 3.3. The average duration in Asymptomatic strata was 192 days and in PGL strata this was 191 days.

The comparison of the base line characteristics on entry to the study are presented in the Table No.1.1 & 2.1. All the subjects had contracted HIV through hetero sexual transmission. 21% were spouses of sexually promiscuous husbands. There was no significant difference in the placebo and verum groups, in either strata, in relation to age distribution, body weight, immune status, or the routine haematological values.

The haematological status showed that absolute numbers of WBC, granulocytes and agranulocytes tended to vary among individuals as evident by standard deviation. Thus when extrapolated, it is expected that the same phenomenon is probable with absolute $CD4^{+ve}$ and $CD8^{+ve}$ T-lymphocytes and was observed to be true. However, this was not considered abnormal given the wide difference in normal ranges for white blood cell counts and CD4 cell population. The normal ranges of CD4 lymphocytes in Indian healthy adults was not available so far. Multicentric studies[17] in three geographically distinct sites showed the normal counts for healthy adults to be in the range of 355/$mm^3$ - 1213/$mm^3$ for CD4 lymphocytes. For CD8 lymphocytes this was in the range of 208/$mm^3$ to 796/$mm^3$. In our study, it was noted that for the same clinical status, the CD4 counts showed wide variations among individuals. Cases were registered in absolute asymptomatic status with counts as low as 263 cells/$mm^3$ and as high as 1049 cells/$mm^3$ in PGL. The study duration was not sufficient for us to observe whether subjects with



lower counts progressed faster to a subsequent clinical stage or whether subjects with healthy counts behaved otherwise.

In the PGL strata, the comparison of out come measures *within* the placebo group at entry and conclusion of trial showed no significance in $CD4^+$ and $CD8^+$ T-Lymphocytes. (Table 2.2). Similar results were also observed in body weight and haematological profiles. Where as within the verum group (Table 2.3), $CD4^+$ T-Lymphocytes exhibited a positive treatment association ($p < 0.01$) by a significant increase from the pre-trial levels. Significant elevation in $CD8^+$ T-Lymphocytes ($p < 0.05$) could also be observed from the table. Other changes in the haematological parameters and body weight were not significant, the means indicated that they were maintained within normal limits. A comparison was also made *between* the control and the active groups. (Table 2.4). Though a clear difference between the means of CD4 (Placebo = 452 Verum = 534) and CD8 (Placebo=1298.50 Verum = 1327.25) observed, the p (0.52 for CD4 and 0.98 for CD8) was not significant. A high variation in the standard deviation between control and verum groups could contribute to such insignificance.

In the asymptomatic strata, the outcome measures either *within* placebo group (Table 1.2) or *within* the verum group (Table 1.3) were not significant. A comparison *between* the groups also was not significant (Table 1.4). Neither the results establish marked difference in pre and post study immunological and haematological values, which shifted within the normal ranges for a specific parameter.

The response of the placebo and verum groups to the treatment was further assessed by analysing the *change* in the $CD4^+/CD8^+$ T-Lymphocytes from pre-trial levels. This exclusive analysis for immunological parameters was separately carried out for Asymptomatic & PGL strata and a third analysis for a pooled strata of the two. In the PGL strata, the verum group showed significant difference in absolute CD4 cell numbers from pre trial levels ($p=0.04$), while the same significance was not observed for CD8 cell numbers ($p=0.75$). In Asymptomatic and combined strata no significance for $CD4^+/CD8^+$ T-Lymphocytes was observed. (Table 2.5)

25 different homoeopathic remedies have been prescribed basing on the totality of symptoms obtained through patient interviews and after consulting repertorial analysis. Homoeopathic potencies used were 6x, 30C, 200C, LM3, LM5. The frequency of repetition of centesimal scale potency ranged between once every day to 3 times a day. High centesimal potencies were not prescribed by the co-investigators because of dose repetition problem. LM potencies were prescribed in water doses 3 to 4 times a day. The control group received placebo looking exactly similar to the form of medication received by the verum group. The most commonly prescribed list of remedies were represented in Table: 3.1. Due to randomization, equal representation of a given remedy in placebo and verum group could not be achieved. The symptom totality for these cases was represented as mental, physical generals and particular symptoms for each remedy in Table No. 3.2. Expressions more frequently observed were italicised.

## DISCUSSION & CONCLUSION

It was not within the scope and objective of this study to ascertain the molecular basis for the immunomodulatory action of homoeopathic medicines or offer an explanation for mechanism of action. The study was limited to observe changes in base line immune level by the variation in absolute numbers of $CD4^{+ve}$ & $CD8^{+ve}$ T-Lymphocytes. Other immunological predictors like ß-2 Microglobulin, Neopterin, and virologic marker of quantification of HIV- RNA by PCR are also equally important in the prognosis of an HIV infected individual. At the time of this study, these facilities were not readily available to us and could not be included in the study design.

Further, the objective of the study was to evaluate the role of the system of homoeopathic therapy rather than to evaluate or suggest any single homoeopathic rem-

edy for the HIV disease. Larger trials in future may suggest a sub group of remedies that are more often indicated in HIV infection.

Though there exists no clear difference between Asymptomatic and PGL stages, either clinically or epidemiologically, we have chosen to conduct the study in two separate strata by following the CDC classification system.

In the normal course of HIV disease, the CD4 T-Lymphocytes tend to remain stable for prolonged periods during asymptomatic phase[18], while the individual maintains normal health status, free from clinical problems. The decline in $CD4^+$ cell numbers is a gradual phenomenon[19]. Little variation is seen in their numbers over a short period of time. This perhaps explains the non-significance of the results in asymptomatic cases: the study period was only 190 days. Longitudinal studies are required to address these questions. Prolonged studies on placebo however is unethical and compounded with problems of long term patient compliance.

Additionally, the problem with asymptomatic cases is a lack of precise prescribing totality which includes characteristic/key note symptoms. The physician must heavily rely on constitutional attributes, generalities and previous and family history of the patient. These too, on many an occasion may not indicate a clear choice of a specific homoeopathic remedy and the distinction between many polychrest remedies that come upon repertorization become difficult. Prescription in such an instance becomes presumptive rather than a certainty, and success or failure of the selected remedy is indicated only on serial repetition of CD4 counts, in the absence of demonstrable aberration in health.

The statistically significant positive influence on $CD4^+$ cell numbers of homoeopathic medicines in the PGL stage does indicate beneficial role in symptomatic phase. Corresponding significant elevation in $CD8^{+ve}$ cell numbers with the treatment, as evident in within the group analysis, also is a noteworthy observation. While the $CD4^+$ cell numbers are unequivocally associated with survival, the role of $CD8^{+ve}$ cells cannot be undermined. It is now clear that $CD8^{+ve}$ T-Lymphocytes are key components of body's immune response against HIV, complementing antibody production. These cells are also proved to be controlling the infection in vitro.[20]

The institute in the past had conducted open trials on HIV disease in various stages of the CDC classification system. The results of these cases could not be compared with the trial cases for want of sufficient number of cases, comparable in terms of clinical stage, base line factors and repeat $CD4^{+ve}$ counts at specified intervals. This happened because of differences in the study designs, which depended on availability of facilities for investigations at the corresponding periods of study. Therefore, consistency or otherwise of the outcome measures in this placebo controlled trial with other open studies could not be established.

In the light of the observations made in this study it is felt that future trials in this area should involve a larger sample size, in order to overcome the problem of high individual variations in immunological and haematological profiles. Other cellular, serological and virological predictors also must be included in the study design to establish the relationship of various predictors and their response to the treatment. Perhaps, no other study deserves such serious ethical considerations as required in the placebo controlled trials in HIV infection. Nevertheless, larger, carefully designed longitudinal and multi-centric studies with pre-determined end points, in various stages of the infection are needed to prove the efficacy of the therapy.

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# Homoeopathic Vaccines: A Possible Approach in Treating HIV/AIDS

**KEY-WORDS:** One plus & one minus make minus, but two minuses make a plus.

**MATERIAL USED:** Human milk and human blood, collected from two young mothers, both around 30-32 yrs; one a patient of nipple cancer, the other full-blown AIDS. Both were treated by the author.

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**INTRODUCTION:** AIDS is an infection caused by HIV, a retro virus, which infects human cell bearing the CD4 surface marker, and causes gradual loss of immunity. During dormant state, virus hides inside genome. Genome is smaller than cell, the structure of virus is also very small, and a number of viruses can be accommodated inside the genome. A genome of virus also called as 'virion'.

Virions multiply through an enzyme, 'Reverse Tran-