



Multicentric Evidence Of Immunological & Clinical Improvement With Low Cost Immunomodulatory Indigenous Medicine In HIV Disease

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OBJECTIVES: Cost of ARV, their adverse events on long term use & development of resistance, limit their use in resource poor settings like India. Discovery of latent reservoirs of HIV have implicated life long therapy with currently available ARV drugs. Therefore alternative therapeutic options aimed at potentiating host immune response with use of immune based therapies or herbal drugs are being explored. This study aims to validate the clinico-immunological efficacy of an orally administrable herbomineral formulation (Reimun) comprising of immunomodulatory drugs in HIV disease in multi-centric settings.

METHODS: This was a multi-centric, open labeled study. HIV positive adult patients of either sex attending our Private Clinics or Public Hospital, between 1 to 15 Jan, 2000 not affording ARV and opting for Reimun alone were included in this study & are followed up to a year. Patients were counseled regarding HIV disease, available ARV therapy & Reimun. Baseline investigations included clinical examination, blood chemistry, liver & renal chemistry. Primary outcome measure was the change from the baseline in absolute CD4 lymphocyte counts during the entire course of the study. CD4 lymphocyte enumeration was done at baseline & repeated at 3 months interval.

Secondary outcome measures included clinical assessment, Karnofsky performance score, occurrence & severity of opportunistic infections. The Primary metric for all analysis of all immunological & laboratory measurements was AUC of all post baseline measurements minus the baseline value (DAVGT) using Van Elteren test.

RESULTS: 1) Out of 72 new patients attending our Private Clinics 49, 20 & 3 patients and out of 184 new patients attending Public Hospital 61, 2 & 122 opted for Reimun, ARV or no therapy respectively. 2) Marked clinical improvement was seen in patients receiving Reimun without any significant untoward effect. There was improvement in appetite with a mean weight gain of 5.2 kgs by the third month ($p < 0.05$), after which the weight stabilized. The mean Karnofsky performance score also improved from baseline value of 6.7 to 8.5 at the end of 1 year, 15 patients were lost to follow-up. 3) Immunological improvement was seen co-relating with the clinical improvement & the mean increase in absolute CD4 count was 40.54, 110 & 117 cells at 3 ($n=110$), 6 ($n=108$), 9 ($n=95$) & 12 ($n=95$) months above the baseline value respectively ($p < 0.02$). 4) 1 patients developed herpes zoster, 2 oral candidiasis & 4 Pulmonary TB. However all these patients responds to the standard therapies for these OIs. 5) The compliance was good though patients went on drug holidays intermittently. These cases showed a decline in CD4 counts that was restored on resumption of therapy.

CONCLUSIONS: Patients on immunomodulatory indigenous medicine (Reimun) showed clinico-immunological improvement. This medicine is affordable to the larger HIV population & is well accepted.