

**An interim account of progress in the observational trial started on 20.02.07 at Ngouso Clinic, Yaounde, Cameroun, looking at the effect of a dietary supplement of Lucerne Leaf Concentrate (LLC) on AIDS patients who are not on retroviral treatment.**

**Situation on 20.08.07 after 6 months**

**Sponsor : APEF** – the Association for the Promotion of Leaf Concentrate in Nutrition

**Methodological support :** - Professor Eric Bertin, nutritionist at Reims University Hospital

**Investigator :** - Dr Bernadette Nah, resident at Ngouso Clinic.

**Object :** Feasibility study of the potential benefit to be had from the consumption of LLC by HIV +ve patients not on anti-retroviral drugs.

**Protocol:** 30 HIV+ subjects, aged 21 or more, were randomly allotted to 3 groups: 10 received 10 g/day LLC (group LLC 10); 10 getting 15 g/d (group LLC 15); and 10 receiving none (Control group); all 3 groups received 500 g rice/d. The distribution of rice and LLC was made thrice weekly. The planned duration was 4 months but, in view of the results at that time, it was decided to extend it to 8 months.

**Inclusion criteria ( ALL to be satisfied ):**

- Age 21 years or more
- HIV+ without anti-retroviral treatment at the date of inclusion or recently
- Anaemic – Haemoglobin (Hb) level = 11 g/dl or less
- Informed consent to participation

**Exclusion criteria ( any ONE suffices ):**

- HIV+ but susceptible to benefit from short-term retroviral treatment
- Pregnancy
- Cancer
- Tuberculosis

**Parameters analysed :** Estimation of the efficacy of LLC is based upon analysis of the following :

- subjective evaluation of the state of health
- anthropometric data: weight, height, BMI (body mass index)
- presence of pathologies: respiratory, digestive and/or infectious
- major events: death or hospitalization
- biological markers at outset and after 2, 4, 6 & 8 months: Hb, levels of CD4 lymphocytes and C-reactive protein

The following table summarises the main clinical and biological observations on the Control Group and the two LLC groups (after 2 weeks group LLC 15 and LLC10 were combined and averaged because both were responding well with no adverse side effects) at the outset (baseline data) and at 2, 4 & 6 months. The next figures will be for 8 months, i.e. the situation at 20.10.07.

**Observational trial of the effect of Lucerne Leaf Concentrate  
on HIV+ subjects  
conducted at Ngouso Health Centre, Yaounde, Cameroon**

**Summary of results with and without LLC  
(all measures are averages for the respective groups, details for individual  
subjects are available on request together with Dr Nah's opinions on the  
progress at each stage)  
from 20.02.2007 to 20.08.2007**

Group	Sex	Date	Weight kg	Hb	CD4	CRP	F*	A**	General Health	Fever	Diarrhoea	BMI
Control N = 10 500 g rice, no LLC	5 M + 5 F	20.02	66.3	8.7	392	10.9	1.3	0.3	1.1	5	0	22.3
		20.04	65.6	9.2	392	10.4	1.0	0.5	1.1	4	0	22.0
		20.06	64.2	9.4	391	10.6	1.1	0.5	1.1	3	2	21.5
		20.08	62.5	9.1	389	10.6	1.6	0.4	1.2	4	2	21.0
		change in 6 months	-3.8	+0.4	-0.3	-0.3	+0.3	+0.1	+0.1	-1	+2	+1.3
Group LLC N = 20 500 g rice, 10 or 15 g LLC	6 M + 14 F	20.02	58.4	8.1	381	14.6	2.0	0.1	0.7	11	7	20.0
		20.04	63.3	13.0	396	9.6	0.1	1.6	1.5	1	1	21.7
		20.06	65.2	15.1	405	8.0	0.1	2.4	1.9	0	0	22.3
		20.08	67.5	15.7	411	7.5	0.1	2.7	1.9	0	0	23.1
		change in 6 months	+9.1	+7.6	+30	-7.1	-1.9	+2.6	+1.2	-11	-7	+3.1

Normal values : Hb (haemoglobin), >12; lymphocytes CD4, 350 – 1600; C reactive protein, <6;  
BMI (body mass index), <18.4 = malnourished; 18.5 – 24.9 = normal; >25= obese.

- Fatigue : 0 = absent; 1 = mild; 2 = moderate; 3 = severe.
- \*\* Appetite: 0 = weak; 1 = fair; 2 = good; 3 = hearty.
- General Health : 0 = very poor; 1 = poor; 2 = fair; 3 = good; 4 = excellent.

**Dr Nah's provisional conclusions after 6 months' supplementation :**

The current experiment at Ngouso Health Centre showed that by the second month the LLC had sensibly improved the general state of health and the quality of life of the seropositive subjects. This improvement continued as shown by the results after 6 months.

The elimination of anaemia is remarkable. The impact on bacterial infections and inflammatory ailments was rapid and encouraging.

The small increase in CD4 at 2 months may not be significant, but it is noticeable that this rise continued, albeit more slowly, through the 6<sup>th</sup> month.

**APEF and Prof. Bertin have decided to continue the study for it is important to verify the continuation of the LLC group's progress, with respect to that of the Control group : this initial evaluation would appear to justify a much broader study to decide whether LLC does have a genuine positive impact on those who are HIVseropositive.**