

## CHAPTER V

### RESULTS

#### 5.1 Characteristics of the Study Population

A total of 40 HIV-positive patients were enrolled from all 156 patient in Klinik Seroja Gunung Jati Hospital that received Antiretroviral Therapy. There were 15 women and 25 men who was diagnosed HIV-positive and received Antiretroviral Therapy enrolled as participants. All participants strictly followed the study protocol and the time schedule during the study period. According to the participants own report, investigators daily observation, and the results of physical examination, no adverse events occurred in both group.

Participants were randomized : 20 in the treatment group who received 2400 mg mangosteen (*Garcinia mangostana*) peel extract and 20 in the placebo group who received placebo for 30 days. There were no significant differences in both women and men that enrolled in mangosteen extract group and placebo group as shown in table 5.1.

**Table 5.1 Demographic Characteristic of the study group**

	All		Mangosteen extract		Placebo	
	n	%	n	%	n	%
<b>Woman</b>	15	37.5	8	40	7	35
<b>Man</b>	25	62.5	12	60	13	65
<b>Total</b>	40	100	20	100	20	100

The baseline characteristics of the remaining 40 subjects in both the treatment and the placebo groups are shown in table 5.2. At baseline, the two groups did not differ significantly in terms of age, body weight, time of ART used, CD4<sup>+</sup>T cells, Total Lymphocyte Counts (TLC) and Haemoglobine (Hb).

**Table 5.2 Baseline Characteristics of Study Group**

<b>Characteristics</b>	<b>All participants (n=40)</b>	<b>Mangosteen extract group (n=20)</b>	<b>Placebo group (n=20)</b>	<b>p</b>
<b>Age (mean±SD)</b>	34.1 ± 5.93	33.25 ± 5.17	34.95 ± 6.63	0.464
<b>Body weight (kg±SD)</b>	58.23 ± 11.11	58.3 ± 10.6	58.15 ± 11.87	0.828
<b>Time of ART used (years±SD)</b>	3.5 ± 52.3	3.1 ± 2.31	4.0 ± 2.27	0.135
<b>CD4<sup>+</sup> T cells (cells/mm<sup>3</sup>±SD)</b>	406 ± 148	373 ± 28	438 ± 36	0.172
<b>TLC (cells/mm<sup>3</sup>±SD)</b>	2066 ± 728	1958 ± 591	2175 ± 844	0.104
<b>Hb (gr/dL±SD)</b>	12.8 ± 1.8	12.84 ± 1.8	12.88 ± 1.9	0.585

## 5.2 Analysis of the results

### 5.2.1 Analysis of CD8<sup>+</sup> T cells

Changes in the number of CD8<sup>+</sup> T cells were observed and shown in table 5.3. After the intervention, the frequency of peripheral blood CD8<sup>+</sup> T cells decreased in both groups. But the decreased was not significant in extract group (p=0.601) neither in placebo group (p=0.135).

**Table 5.3 Pretest-Post test analysis results for CD8<sup>+</sup> T cells by wilcoxon test**

		<b>N</b>	<b>Median (minimum-maximum) cells/mm<sup>3</sup></b>	<b>p</b>
<b>Extract</b>	Pretest	20	771.5 (376-1692)	0.601
	Posttest	20	711.5 (363-1865)	
<b>Placebo</b>	Pretest	20	932 ( 374-2260)	0.135
	Posttest	20	829 (373-2125)	

Decrease in the number of CD8<sup>+</sup> T cells in the extract group present in 11 people, and in the placebo group there were 14 people who experienced a decrease in the number of CD8<sup>+</sup> T cells.

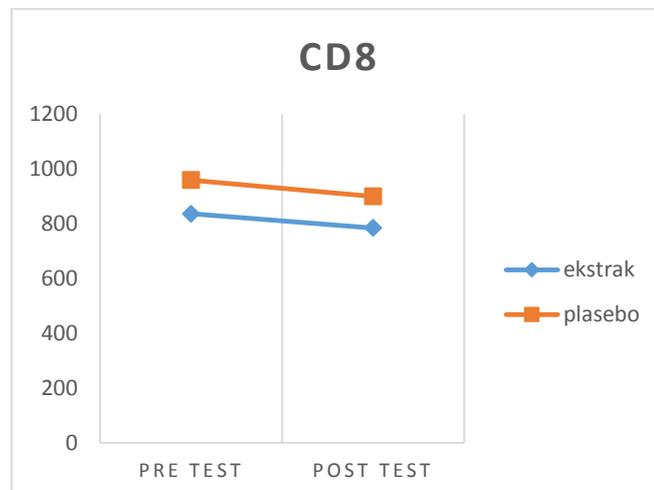
At the end of the study, the CD8<sup>+</sup> T cells decreased in the extract group was compared to the placebo group as shown in table 5.4. There were no significant differences changes of CD8<sup>+</sup> T cells between extract group compare to placebo group (p=0.703)

**Table 5.4 Mann-Whitney analysis of CD8<sup>+</sup> T cells between extract group and placebo group**

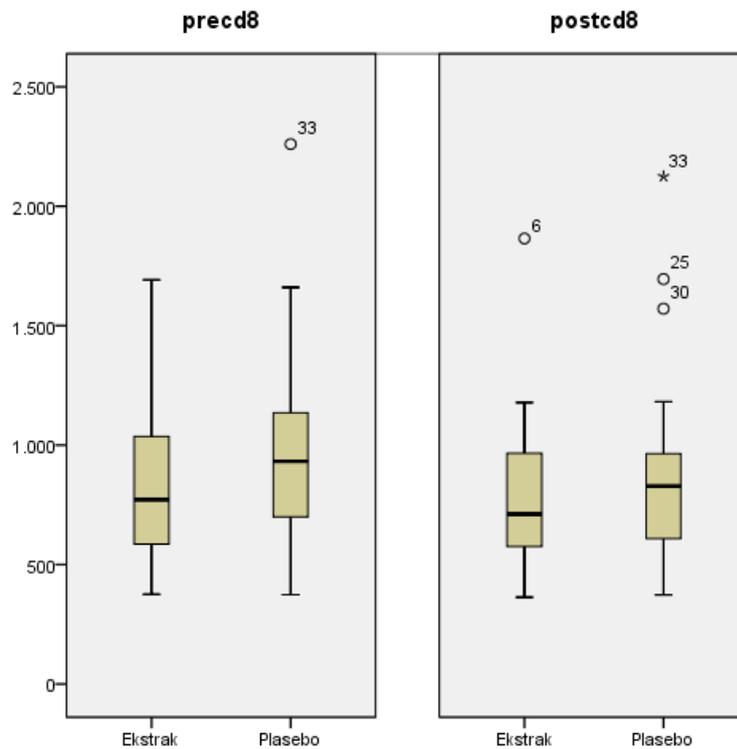
		N	Median (minimum-maximum) cells/mm <sup>3</sup>	p
<b>Pretest</b>	Extract	20	771.5 (376-1692)	0.812
	Placebo	20	932 ( 374-2260)	
<b>Posttest</b>	Extract	20	711.5 (363-1865)	0.703
	Placebo	20	829 (373-2125)	

Mann-Whitney test, mean rank post test extract 19.20 and mean rank placebo 21.80.

There were a decrease in the number of CD8<sup>+</sup> T cells on both group as follow in fig. 5.1, but the decrease was not statistically significant.



**Fig. 5.1 The comparison of CD8<sup>+</sup> T cells changes**



**Fig. 5.2 Boxplot of CD8<sup>+</sup> T cells changes comparison**

Delta decline of the number of CD8<sup>+</sup> T cells from extract group is 51.65 which is 0.87 times lower than delta of the placebo group whose delta is 59, or delta decline of placebo group 1.14 times higher than delta of extract group.

There is an increase in Th/Tc ratio between baseline and post treatment. In the extract group Th/Tc ratio increase from 0.44 to 0.51, and 0.45 into 0.54 in the placebo group.

### 5.2.2 Analysis of CD8<sup>+</sup>CD38 Expression

Changes in the level of CD8<sup>+</sup>CD38 expression were observed and shown in table 5.5. After the intervention, the level of CD8<sup>+</sup>CD38 expression decreased both two groups. The decreased was significant in extract group (p=0.001) either in placebo group (p=0.001).

**Table 5.5. Pretest-Post test analysis results of CD8<sup>+</sup>CD38 by wilcoxon test**

		N	Median (minimum-maximum) %	p
<b>Extract</b>	Pretest	20	9.72 (4.6-21.11)	0.001
	Posttest	20	6.77 (1.8-17.39)	
<b>Placebo</b>	Pretest	20	10.05 (5.19-56.40)	0.001
	Posttest	20	6.83 (2.26-56.21)	

At the end of the study, CD8<sup>+</sup>CD38 decreased in the extract group was compared to the placebo group as shown in table 5.6. There were no significant difference changes of CD8<sup>+</sup>CD38 expression between extract group compare to placebo group (p=0.495)

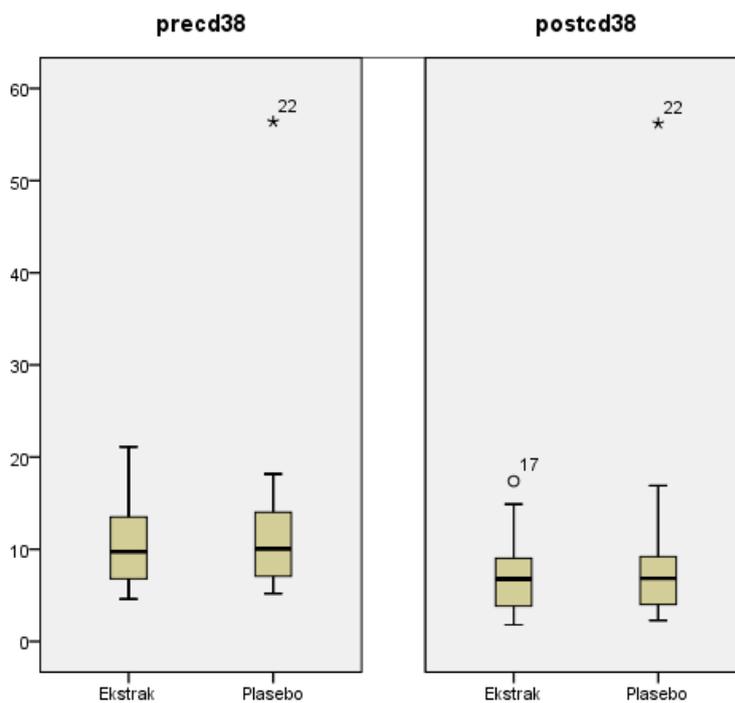
**Table 5.6 Mann-witney analysis of CD8<sup>+</sup>CD38 between extract group and placebo group**

		N	Median (minimum-maximum) %	p
<b>Pretest</b>	Extract	20	9.72 (4.6-21.11)	0.429
	Placebo	20	10.05 (5.19-56.40)	
<b>Posttest</b>	Extract	20	6.77 (1.8-17.39)	0.495
	Placebo	20	6.83 (2.26-56.21)	

Decrease on CD8<sup>+</sup>CD38 expression in the extract group present in 19 people, and in the placebo group all people experienced a decrease on CD8<sup>+</sup>CD38 expression, there were a decrease on CD8<sup>+</sup>CD38 in both group from pretest to post test as follow in fig. 5.3 which is statistically significant, but no significant differences of changes between extract group compare to placebo group (shown in fig. 5.4).



**Fig.5.3 The comparison of the level of CD38 expression**



**Fig. 5.4 Boxplot of CD8+CD38 expression comparison**

Delta decline of the level of CD8+CD38 expression from extract group is 3.23 which is 1.035 times higher than delta of placebo group whose delta is 3.12 or delta decline of placebo is 0.96 times lower than extract group.

### **5.2.3 Subjects self-reported improvement**

According to the subjects self-report, 15 patients (75%) in the treatment group reported improvement in health status after intake of mangosteen peel extract versus 9 patients (45%) in the control group which intake placebo. Furthermore, among those who reported the improvement in the extract group, 70% patients felt their body healthier, 25% patients reported it was easier in their defecation and 35% patients reported that their appetite increased.