

## Chapter 2

### RATIONALE AND OBJECTIVE

There is no little doubt that the palliative use of megestrol acetate to stimulate appetite and weight gain in cancer anorexia-cachexia has been successful. One major concern is the price that has been paid to render the benefit of weight change. No previous study was done to determine the efficacy of a lower than 160 mg/d dose. Although there were some studies that found a positive correlation between weight gain and dose of megestrol acetate, the higher dose may cause more side effects and cost<sup>63,64</sup>. Percent of patients with actual weight gain in those studies were 28-35% and 43-64% in the 160 and 800 mg/d study arm, respectively. It is interested to know that whether the lower dose is as effective as conventional dose. From the available forms of megestrol, it is convenient to pick up the 40 mg/d dose to test its efficacy. If there were certain number of patients who responded to the lower dose, it should be an attractive starting dose due to the lower expense.

Objective improvement that readily determines the efficacy of tested drug should be the body weight change. However, it is interesting to know the altered body compositions in the course of study. Anthropometric measurement can serve as an indirect evidence of body compositions that can be easily performed<sup>66</sup>.

Because there is no clear benefit on tumor response or survival by orexigenic agent in patient with cancer anorexia-cachexia, patient's acceptance and family concerns should be co-evaluated. This study would not be complete without measuring the psychological aspects of patient in term of quality of life. However, at the present time there is not one non-arbitrary means to assess this issue. Quality of life assessment should be a multidimensional evaluation which also includes certain aspect of concerns<sup>67</sup>. Moreover it should be a short test proved to be reliable and valid<sup>68</sup>. Based on

the prior discussed factors, Functional Assessment of Cancer Therapy (FACT) was selected to be the model used for quality of life assessment<sup>69-71</sup>. A slight adaptation to Thai language was done (see Appendix III).

### Research Question

Do low dose megestrol acetate have different responses on weight gain and appetite in patients with cancer anorexia-cachexia?

### Objectives

1. To determine therapeutic efficacy of low dose megestrol acetate in term of weight, nutritional status, appetite stimulation, and short term survival.
2. To determine the appropriate dose of megestrol acetate in the management of cancer anorexia-cachexia syndrome by comparing two different doses.

### Hypothesis

H<sub>0</sub> (Null hypothesis) = The mean body weight change of the 40mg/d study arm is equal to that of the 160mg/d study arm (mean WC<sub>40</sub> = mean WC<sub>160</sub>).

H<sub>A</sub> (Alternative hypothesis) = The mean body weight change of the 160mg/d study arm is higher than that of the 40mg/d study arm (mean WC<sub>160</sub> > mean WC<sub>40</sub>).

### Clinical Implication of the Study

1. If the 40 mg/d dose of megestrol acetate was proven to be effective in alleviation progressive weight loss in cancer patients, it would be used as an initial dose as a palliative treatment of cancer anorexia-cachexia. With the

lower cost and available dosage, 40mg/d dose might become the standard dose.

2. Alteration of anthropometric measurement data may serve as the information for body composition changed during the course of cancer anorexia-cachexia and may contribute to future study.
3. Quality of life assessment may be proved useful as a model of multidimensional evaluation in cancer patients regarding patient's physical, emotional, and psychological perception influenced by disease and treatment.