

**THE EFFICACY OF MALUNGGAY (*Moringa Oleifera*) GIVEN TO NEAR TERM PREGNANT WOMEN IN INDUCING EARLY POSTPARTUM BREAST MILK PRODUCTION – A DOUBLE BLIND RANDOMIZED CLINICAL TRIAL**

Glezel Briton-Medrano, M.d., Ma. Lucila Perez, M.D.

**OBJECTIVES:** To determine the efficacy of malunggay capsules given antepartum in inducing early breastmilk production and compare the amount of milk produced two days postpartum among the groups.

**STUDY DESIGN:** Double-blind, randomized controlled clinical trial

**INTERVENTION:** Pregnants on  $\geq 35^{\text{th}}$  wk AOG consulting at Ospital ng Makati with regular prenatal checkup and no medical problems were randomized to groups: Group A received placebo and group B Malunggay capsules 350mg/capsule, both took 2 capsules 3x a day for  $\geq 3$  days until delivered. Breastpumping was done on the 6<sup>th</sup> hour postpartum and every 4 hours until the 46<sup>th</sup> hour. The following outcomes were noted: (1) onset of production; (2) amount produced; (3) effect of duration of intake with the amount and onset of produced.

**RESULTS:** The malunggay group showed earlier onset of significant (10ml) and adequate amount (30ml) of breastmilk. The Malunggay group also showed a threefold greater amount of breastmilk produced at onset and a 228% increase in average total amount in the first 24 hours after delivery (Placebo = 28.2 ml; Malunggay = 64.2 ml). Results show that longer duration of intake led to greater breastmilk production and earlier onset, this was non-significant.

**CONCLUSION:** Malunggay capsules given antepartum ( $>35$  wks AOG) until delivery is an effective galactagogue resulting to earlier onset of lactation with greater amounts of breastmilk produced.

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**INTRODUCTION:**

“ A newborn baby has only three demands. They are warmth in the arms of its mother, food from her breasts, and security in the knowledge of her presence. Breastfeeding satisfies all three. “ – Dr. Grantly Dick-Read.

Breastfeeding is promoted by the DOH and WHO. They have made most of the hospitals “Baby Friendly” meaning that breastfeeding is exclusively given to all newborns. After birth, it is the umbilicus, a living link between the mother and the child. The only problem is that breast milk is only produced 24-72 hours after delivery – one of the reasons why most mothers shift or start their babies with a milk formula

In 1991, the Department of Health reported 85% of mothers initiated breastfeeding soon after delivery but only 22% of these mothers are still exclusively feeding by one month old (1). Most mothers after initiating expression of breast milk on the first few days postpartum complain of insufficient volume of breast milk. According to Nichols F.H., it takes 3-4 days postpartum for the establishment of adequate milk supply. This has prompted mothers to shift their children to bottle-feeding and stop breastfeeding (8).

Galactagogues are herbs that promote and establish the flow of mother’s milk. Malunggay is one of the most studied herb here in the Philippines, but usually promoted to be given postpartum or after delivery to induce and increase breast milk production. No available literature however, reports of its use prior to delivery to induce earlier onset of breast milk production.

**GENERAL OBJECTIVES:** To determine the efficacy of malunggay capsules in inducing early breast milk production if given prior to delivery to pregnant women.

**SPECIFIC OBJECTIVES:**

1. To compare the onset of breast milk production among those given malunggay capsules and placebo prior to delivery.
2. To compare the amount of milk produced among those given malunggay capsules and placebo for the first two days after delivery.
3. To determine if the duration of intake of malunggay capsules would have an effect on the onset and amount of breast milk produced.
4. To determine the adverse effects of malunggay capsules among mothers and newborns if given during the antenatal period.

**METHODOLOGY:**

Research Design: Double-blind randomized clinical trial

Setting: Ospital ng Makati (OSMAK)

Subjects:

Pregnant women consulting for prenatal check-ups are the target population of the study. They were recruited consecutively if they fulfilled the following criteria:

**Inclusion Criteria:** All pregnant women at least 35 weeks age of gestation with regular prenatal checkups ( $\geq 4$  PNCU) at the OB - GYNE Out-Patient Department OSMAK.

**Exclusion Criteria:** Pregnant women  $\geq 4$  gravida with history of abortion or still births, with maternal conditions that would have an effect on breast milk production and contraindications to breastfeeding (e.g. advanced pulmonary tuberculosis, extra-pulmonary spread of TB, Rubella, renal problems, fever, retracted nipples, anemia, and pneumonia )

**Intervention:**

Pregnant women eligible for the study were examined to determine if they fulfilled the inclusion and exclusion criteria and complete blood count (CBC) was taken to determine the presence of anemia (Hgb  $\leq 10.5$  mg/dl). Data on age, level of education and pregnancy history were noted.

Once eligible, they were asked to sign an informed consent (Appendix 1) and were randomized to two groups. Randomization using the table of random numbers was prepared prior to the start of the study. An assigned third party gave each subject a sealed envelope which had been arranged according to the prepared randomization sequence. Each sealed envelope contained a week's supply of either the placebo for group 1 or the malunggay capsules (Prolacta) for group 2.

Each malunggay capsule contained 350mg of powdered malunggay leaves. Placebos provided had the same appearance as malunggay capsules (Prolacta). They were instructed to take 2 capsules 3 times a day for one week. On the next follow-up one week later, another set of placebo or malunggay capsules was given. Once the mothers gave birth, intake of the malunggay capsules or placebo was discontinued.

The subject was instructed not to take other drugs or food with known breast milk-inducing or reducing action. A list was provided of these drugs and foods (Appendix 3)

## **REVIEW OF RELATED LITERATURE:**

"Moringa Oleifera" or more commonly known as Malunggay is one of the most common plants in the Philippines used as a galactagogue. Its medicinal parts are the leaves, roots, pod, and flowers. It is planted throughout the country in settled areas at low and medium altitude. Its leaves can be harvested throughout the year. Fruiting season is from February to April annually (6). Its leaves are rich in calcium, iron, phosphorous, and 17% of protein (5,6).

In the Philippines, it is also used for sores, ulcers, snakebites and it is anti-scorbutic. Its known adverse effects were seen from root extracts such as; hepatological, hepatorenal effects, potential anti-fertility effects and mutagenic activity of ethanol extracts from roasted seeds.

As galactagogues, dried malunggay leaves in encapsulated form are available commercially. Studies have shown the following pharmacological effects : higher prolactin levels after 48 hours in breastfeeding mothers and significant weight gain among babies; and an increase in the volume of breast milk. (2,3,4).

This study aims on giving a galactagogue in the form of malunggay capsules during the antenatal period to induce earlier lactation in the first two days of life and increase the amount of breast milk during the first 24 hours.

## **HYPOTHESIS:**

Null Hypothesis: There is no difference between malunggay capsules and placebo in inducing early breast milk production if given prior to delivery.

Alternative Hypothesis: There is difference between malunggay capsule and placebo in inducing early breast milk production.

Outcome:

After delivery, demonstration with training regarding the use of battery/electric breast pump was done. During the two-day observation period mothers were instructed not to breastfeed their child directly. On the 6<sup>th</sup> hour after giving birth, mothers were instructed to pump every 4 hours for 10-15 minutes on each breast for 2 days. The following were noted:

A. Onset of breast milk production

After giving birth, the mothers were instructed to note on a standardized data form (Appendix 2) the time of the first milk drip based on the synchronized clocks at OB-ward or recovery room. The time during which a "significant amount" of breast milk is produced was also noted.

B. Amount of breast milk produced

Breast milk expressed through pumping every 4 hours were measured using a standard measuring bottle by the mothers. They were asked to write down the time and amount on a pre-tested standardized data form (Appendix 2). Their technique of breast pumping measurements and recording were monitored. At the time of discharge, the proportion of mothers with "adequate amount" of breast milk was also determined

C. Determination of effect of duration of intake on the onset and amount of breast milk produced

The onset and amount of breast milk produced were tabulated and correlated with the duration of intake of the malunggay capsules and placebo

#### D. Adverse effects

To monitor for the adverse effects during the intake of the drugs, subjects were interviewed at the time of admission for constipation, hypersensitivity reaction or any effects they have noted during the intake of malunggay capsules (Prolacta). Possible effects on delivery were obtained by the author. This was done by checking on the mother's chart such as prolonged labor, early rupture of membranes, etc

Drop outs were defined as:

- a. Subjects who did not have their deliveries at Ospital ng Makati
- b. Subjects who took  $\leq 6$  capsules of malunggay or placebo
- c. Subjects who had medical problems during their labor or deliveries (i.e. eclampsia, pre-eclampsia, etc)
- d. Subjects who delivered babies with poor APGAR score, congenital defects or physical malformations

#### Definition of Terms:

Significant amount of breast milk : amounts expressed  $\geq 10$ ml

Adequate amount of breast milk : amounts expressed  $\geq 30$ ml

Flow of Procedures:

Target population: Pregnant women  
Consulting at OB-GYNE OPD OSMAK

Sample population: >35 weeks AOG  
Regular PNCU

Informed consent  
CBC

Randomized  
Allocation

Experimental group  
(Malunggay capsules)

Control group  
(Placebo)

Delivery

Onset of breastmilk production  
Amount of breastmilk produced  
Adverse effects

Statistical Analysis:

An intention to treat analysis was done.

- A. Baseline characteristics of subjects were reported as proportions or mean  $\pm$  1SD and compared using T test, chi square or Fischer's exact test for quantitative and qualitative categories.
- B. Amount of breast milk produced was reported as mean  $\pm$  1SD. T test and ANOVA test was used to compare the mean amount of breast milk produced in the two groups.
- C. Onset of lactation was reported as mean  $\pm$  1SD. T test was used to compare the mean time of onset of breast milk production.
- D. ANOVA test was done to compare the duration of intake with the amount and onset of breast milk. To correlate, a scatterplot diagram was drawn and Spearman's rank analysis was done.
- E. Adverse effects will be reported as descriptive statistics.

All the results were analyzed for their significance using a 5% significance level.

Sample Size: 26 per group

The final sample of 26/group in this study corresponds to a 95% confidence level or reliability, 65% sensitivity and a margin of error or difference of 9.

## RESULTS

The study was started January 2004-November 2004. There were a total of 96 subjects seen but 14 were excluded and 28 were dropouts. Among the dropouts 11 did not deliver at OSMAC, 14 had inadequate intake, 1 delivered a baby with poor APGAR score (secondary to perinatal asphyxia), 1 refused breast pumping, and 1 had a congenital anomaly (hydrocephalus, meningocoele and spina bifida).

The baseline characteristics of the subjects on both placebo and malunggay groups were comparable (Table 1). Subjects from both groups were 26-27 years old, at 36 weeks AOG and were gravida 1 or 2. Majority reached college level.

Table 1: Comparison of baseline characteristics of placebo and malunggay group

CHARACTERISTICS	PLACEBO GROUP (n=26 )	MALUNGGAY GROUP (n=27 )	P- value
Maternal age (yrs)	27.6 ± 4.8	26.56 ± 5.50	0.46 (NS)
Age of gestation (weeks)	36.1 ± 0.8	36.26 ± 1.10	0.49 (NS)
Gravida	1.8 ± 0.9	1.74 ± 0.90	0.91 (NS)
Educational background:			
High School	5 (19%)	9 (33%)	0.24 (NS)
College	21 (81%)	18 (67%)	

Onset of production of a “significant amount” ( $\geq 10$ ml) and an “adequate amount” ( $\geq 30$ ml) of breast milk between the placebo and malunggay group were significantly different. (Table 2) Malunggay induced breast milk production of “significant” amounts by approximately 11 hours earlier compared to that of placebo and amounts  $\geq 30$  ml 9 hours earlier. The amount of breast milk produced at the start of lactation was of a higher quantity with the initial amount in the malunggay group almost triple that of the placebo.

Table 2: Comparison of the time of onset and amount of breast milk produced at onset in the placebo and malunggay group

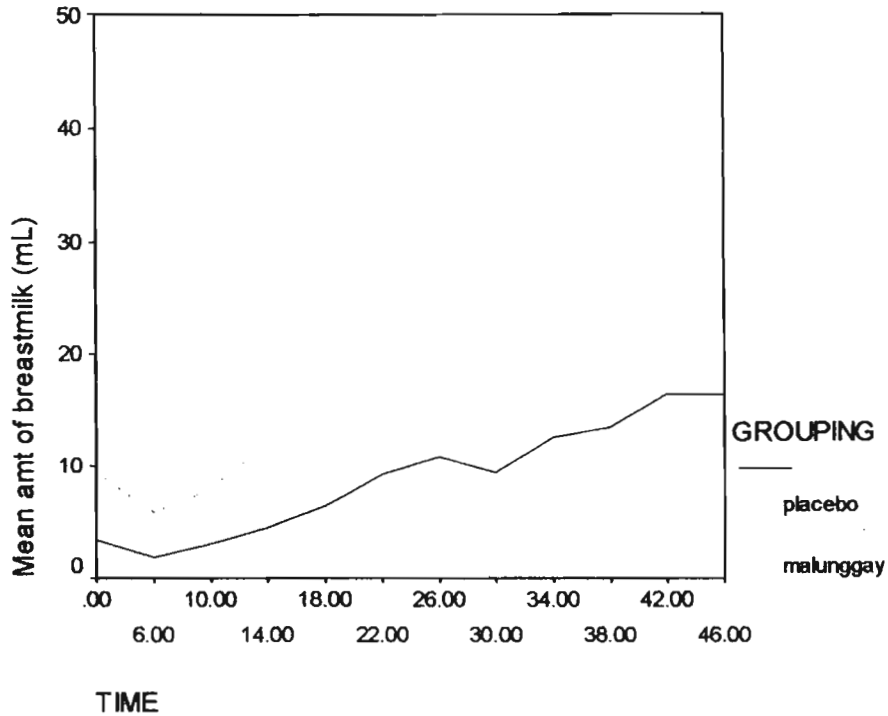
	PLACEBO GROUP (n= 26)	MALUNGGAY GROUP (n= 26)	P-value
Onset of breast milk production (hrs after delivery)*			
$\geq 10$ ml	32.92 $\pm$ 16.12	21.48 $\pm$ 16.42	0.014 (SIG)
$\geq 30$ ml	41.38 $\pm$ 12.46	32.67 $\pm$ 15.95	0.031 (SIG)
Amount of breast milk produced at onset (ml)*	3.44 $\pm$ 4.29	9.17 $\pm$ 7.37	0.001 (SIG)

\*reported as mean + 1SD

Figure 1 compares the amount of breast milk produced between the placebo and malunggay group after delivery. It showed an increasing amount of breast milk production with time in both groups. However, greater increments in breast milk production were seen with malunggay. This increase was noted up to the 42<sup>nd</sup> hour with a drop noted thereafter.



Figure 1: Comparison of the amount of breast milk produced in malunggay and placebo groups after delivery



When total average amount of breast milk produced during the first 2 days was compared in the two groups, the amount collected with malunggay intake was 228% higher and 260% higher in the first and second day, respectively. After 24 hours mothers who took malunggay capsules could produce 64 ml as compared to 28 ml in the placebo group. (Table 3)

Table 3: Comparison of the amount of breastmilk production between the placebo and malunggay group from the time after delivery

Time after delivery breastmilk extracted	Amount of breastmilk		P-value
	Placebo Group (n=26)	Malunggay Group (n=27)	
0 hour	3.4 + 4.3	9.2 + 7.4	0.001 (SIG)
6 <sup>th</sup> hour	2.0 + 4.5	5.7 + 8.4	0.051 (SIG)
10 <sup>th</sup> hour	3.1 + 7.2	7.8 + 10.8	0.072 (NS)
14 <sup>th</sup> hour	4.6 + 8.6	11.8 + 17.3	0.064 (NS)
18 <sup>th</sup> hour	6.5 + 13.5	16.1 + 19.4	0.041 (SIG)
22 <sup>th</sup> hour	9.4 + 16.5	20.2 + 23.7	0.061 (SIG)
26 <sup>th</sup> hour	10.9 + 17.5	22.1 + 27.2	0.085 (NS)
30 <sup>th</sup> hour	9.6 + 16.5	24.5 + 25.6	0.015 (SIG)
34 <sup>th</sup> hour	12.7 + 18.6	33.4 + 43.4	0.029 (SIG)
38 <sup>th</sup> hour	13.6 + 24.6	36.7 + 36.4	0.009 (SIG)
42 <sup>nd</sup> hour	16.5 + 28.1	39.4 + 42.6	0.026 (SIG)
46 <sup>th</sup> hour	16.6 + 30.1	36.5 + 34.7	0.031 (SIG)

Majority of the mothers took malunggay tablets for 7-14 days (53.85%), two subjects took it for 5 days (7.69%) and the rest of the group had it for more than two weeks (38.46%) The study showed that the onset of breast milk production and amount of breast milk produced at onset is not affected by the duration of intake of malunggay capsules. However as seen on table 4, there was a tendency to an earlier onset with greater amount on longer intake of malunggay. Spearman's rank test was also done but showed no significant correlation between duration of intake and onset or amount of breast milk produced



Compliance in the malunggay group was higher than the placebo. Full compliance was reported in only 15.38% and 7.69% respectively. Mostly on both groups have only reached 25% compliance level.

Table 4: Association between the duration of intake of malunggay capsules with the onset and amount of breast milk produced

	Duration of malunggay intake (days)			P- value
	< 7 (n=2)	7-14 (n=15)	>14 (n=10)	
Onset of breast milk production *( hrs after delivery)	17.0 ± 7.1	15.4 ± 11.5	9.4 ± 11.7	0.410 (NS)
Amount of breast milk produced at onset *(ml)	7.5 ± 3.5	8.0 ± 5.9	12.0 ± 9.1	0.388 (NS)

- reported as mean + 1SD

There were no adverse reactions noted by the subjects during their intake of malunggay capsules.



## DISCUSSION

Breast milk is the natural and complete food for infants. It is safe, inexpensive and provides all nutrients most babies need for the first 6 months of life. Researches have shown that breastfed babies are less likely to suffer eczema, food allergy and respiratory illness than formula-fed babies. In the Philippines, 85% of mothers initiated breastfeeding soon after delivery but only 22% of these mothers are still exclusively feeding by one month old (1). Most mothers after initiating expression of breast milk on the first few days postpartum complain of insufficient volume of breast milk. This has prompted mothers to shift their children to bottle-feeding and stop breastfeeding (8).

Galactagogues are herbs that promote and establish the flow of mother's milk. Malunggay is one of the most studied herb here in the Philippines. As a galctogogue, several studies confirm its efficacy. However, it is usually promoted to be given 3 days postpartum or after delivery to induce lactation.

The mechanism of action of malunggay leaves in lactation needs greater examination. A study done in 1997 by Almirante and Lim showed the lactation-enhancing effect of malunggay leaves as evidenced by a greater increase in maternal serum prolactin levels. Prolactin is the most important hormone in the initiation of lactation. However, the prolactin mechanism is contradicted by a recent local study done in 2002 by Co M.A, et.al. which concluded that there's no significant correlation between the prolactin concentration levels in mothers and milk production.

As a galactogogue, several studies confirm the efficacy of malunggay. Gains in the infants' weights among the lactating mothers who took the malunggay leaves after delivery was reported by Almirante and Lim. An increase in the volume of breast milk of mothers of preterm infants by 150-176% on day 5 was noted by Estrella and Mantaring. (4) In these studies however, it was given 3 days after delivery to induce lactation therefore it was only after 4-5 days postpartum that mothers noted increase in breast milk.

The data presented in this study demonstrates the beneficial effect of Malunggay as a galactagogue if given antepartum. It showed that intake of malunggay prior to delivery results in earlier onset of lactation; "significant quantities" ( $\geq 10$  ml) were being produced 20 hours postpartum and quantities were higher by 228% on the first postpartum day than with placebo. These data point to a possible role of malunggay in promoting breastfeeding addressing the problem of insufficient amounts often cited by mothers. More mothers may thus be encouraged to breastfeed after delivery rather than use milk formulas.

After the 42<sup>nd</sup> hour, a drop in amount was seen in the malunggay group probably because the subjects had stopped taking malunggay once they had delivered.

We see a trend for earlier lactation with increasing intake and a direct relationship between the duration and amount of breast milk produced. The duration of intake however did not give a significant p value, this may be due to the small number of subjects enrolled.

No adverse effects were noted during the entire study. This may be because the commercialized capsules contain only 350mg of malunggay leaves. Also, its known adverse effects were seen from root extracts. Possible hepatologic, hepatorenal effects, potential anti-fertility effects and mutagenic activity of ethanol extracts have been reported from roasted seeds.



## **CONCLUSION**

Malunggay capsules are effective galactagogues if given prior to delivery with onset of adequate amount ( $\geq 30\text{ml}$ ) and significant amount ( $\geq 10\text{ml}$ ) occurring earlier compared to that of the placebo group. Higher initial amounts with greater increments of breast milk were produced from the time of delivery compared to that of placebo. The duration of intake does not significantly affect the amount and onset of breast milk production.

No adverse effects were noted during the study.

## **RECOMMENDATION**

It is recommended that a study on the minimum duration of intake needed to produce a galactagogue effect be determined with bigger sample size since the result indicates a positive and beneficial effect of malunggay capsules to pregnant women if taken at least 4 weeks prior to delivery.

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APPENDIX 1  
**PATIENT INFORMED CONSENT**  
**(PAHINTULOT NG PASYENTE)**

PATIENT \_\_\_\_\_ AGE \_\_\_\_\_ ADDRESS \_\_\_\_\_

\_\_\_\_\_  
*Pasyente*

*Gulang*

*Tirahan*

I hereby authorize Dr. Glezel Briton-Medrano the attending physician-investigator and/or the assistant physician-investigator she may designate to perform the following procedure: Giving of malunggay capsules or placebo per orem.

*(Ako ay nagbibigay pahintulot kay Dr Glezel Briton-Medrano and manggagamot na tagapag-siyasat at/o sinumang kanyang itatalaga na gampanan ang sumusunod na proseso:)*

I affirm that :

*(Pinatutunayan ko na:)*

1. I have been informed that malunggay capsules re commonly taken after  
 Delivery to increase *breastmilk* production but no studies yet has  
 been  
 Done on its effects if taken before birth delivery.  
*(Alam ko na ang paginom ng malunggay capsules ay kasalukuyang  
 madals gawin pagkapanganak para dumami ang gatas ng ina, pero  
 wala pang pag-aaral na naisagawa tungkol sa epekto ng paginom  
 nito bago  
 magsilang.)*

2. I have received detailed description of the procedures to be followed.

Upon signing the informed consent a complete blood count will be done.

We will be grouped into two. One group would take 2 malunggay capsules three a times a day until delivery and the other group would take the placebo with the same directions. Upon delivery the intake of either

The malunggay capsule or placebo will be stopped. Adverse effects will

Be noted. The earliest onset of breastmilk drip will be recorded. Breastmilk production will be measured every 4 hours by using a standardized breastpump. Breast pumping will be done 15 minutes in each breast. Measurements will be recorded on a standardized table. Breast pumping will be stopped on the 48<sup>th</sup> hour after delivery.

*(Lubos na ipinaliwanag sa akin ang paraan ng pagraal. Pagka pirma ng pahintulot ako ay kukunan ng complete blood count. Kami ay hahatiin sa dalawang grupo. Ang isang grupo ay iinom ng 2 capsula ng malunggay tatlong beses sa isang araw hanggang sa makapanganak, at isang grupo ia iinom ng plasebo. Lahat ng komplikasyon ay itatanong sa pagsilang.*

*Mula kapangananak aalimin ang oras na unang mapansin ang gata mula sa suso at isusulat sa papel na ibinigay. Bibilanging idin ang dami ng gatas kada apat na oras sa pamamagitan ng pag-breastpump gamit ang isang stndardized breastpump. Bawat suso ay ipa-pump ng 15 minuto ang pagsusukat ng dami ay ihihinto lamang pagkalampas ng 48 hours kapanganak.)*

3. I have been informed that 80 participants will be randomly assigned to

Either malunggay or placebo group. All the participants will have equal chance of being assigned to the two groups by a third person who will not have knowledge of the patient or hospital personnel.

*( 80 ang kasama sa pananaliksik at maaring malagay sa alin man sa dalawang grupo. Lahat ng pasyenteng kasali ay pantay ang tsansa namatakda sa alin man sa dalkawang grupo. Isang tao ay hindi kilala ang pasyente o tauhan sa ospital anf pipiliing tagapagtakda.)*

4. I have been informed of the responsibilities of all the participants and possible reasons for being removed from the study.

*(Alam ko ang mga responsibilidad ng mga nakasali sa pagsusuri at mga dahilan para matanggal sa pagkakasali sa pagsusuring ito.)*

5. I have been given a description of all known effects, discomforts, risks

That may be expected when receiving or not receiving malunggay capsules. The known effects are: abortifacient, constipation, hypersensitivity reaction.

*(Ipinaliwanag na rin ang mga nalalamang di kanais-nais na epekto na maari maranasan kapag uminom ng malunggay capsules kagaya ng :  
pampalaglag, pagtigas ng dumi, allergy.)*

6. I have been given the opportunity to ask the questions concerning the procedure involved, and my doctor have been clearly been willing to answer them.

*( Ako ay binigyan ng pagkakataon na makapagtanong ng ano mang bagay na may kinalaman sa pagsusuri at sinagot naman ng sapat ang aking mga tanong.)*

7. I have been clearly told that I am able to withdraw my consent and stop my participation in this study at any timer and that such withdrawal of consent will not prejudice me. I have been assured that information in which becomes available that may be relevant to my willingness to continue participation shall be given to me.

*(Malinaw sa akin na maaring bawiin ang aking pahintulot at itigil ang aking paglahok sa ano mang oras aking naiisin. Ito ay hindi mamasamain*

*ng aking manggagamot. Pinangako sa akin na anomang bagong impormasyon na may kinalaman sa aking desisyon na lumahok ay ipapaalam sa akin.*

8. I have been assured that the study will be done with appropriate medical safeguards and protection. All cases of adverse reaction Arising from the study shall receive appropriate management. The Main investigator shall be responsible for the treatment of subjects whose complications directly resulted from non-implementation of the procedure.

*(Ang pagsusuri ay paguukulan ng sapat na pagiingat sa kalusugan. Lahat ng magkaka-komplikasyon na bunga ng imbestigasyon ay bibigyan ng kaukulang paggamot. Ang pangunahing tagapag-imbestiga ay siyang tutulong sa pagpapaggamot ng pasyente na nagkakomplikasyon dahil sa pag-inom ng gamot.)*

9. I have further been assured of appropriate safeguards to secure Confidentiality of the patient's identity which will not be divulged Without my written consent.

*(Kaukulang pag-iingat ay isasagawa upang mapangalagaan pagkatao at mahalagang bagay ukol sa pasyente. Ang mga bagay na ito ay hindi isiwalat ng wala akong kasulatang pahintulot.)*

10. The investigation is expected to be finished two days after delivery and I have been assured that I get a copy of the results from the primary investigator if I would like to.

*(Matatapos ang pagsusuri sa loob ng dalawang araw makapanganak. maaring makita ang resulta ng pagsusuri mula sa pangunahing tagaimbestiga.)*

11. I have been informed that only the parent, husband or guardian of the patient shall have the authority to give or withdraw or consent.

*(Ang maari lamang magbigay o bumawi ng pahintulot ay sinoman sa magulang, asawa o tagapag-alaga ng pasyente.)*

12. In case of emergency or questions at the time of participation, I can Contact Dr. Glezel Briton-Medrano at 882-6316 loc 258, the principal investigator.

*(Pwedeng tawagan si Dr. Glezel Briton-Medrano sa telepono 882-6316 loc 258, ang pangunahing tagapag-imbetiga kung may emerhensya o mga tanong tungkol sa imbestigasyon.)*

Signature/Lagda \_\_\_\_\_

Patient or Guardian

(Pasyente o Tagapangalaga)

\_\_\_\_\_  
Physician – Investigator

\_\_\_\_\_  
Relationship/Kaugnayan

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

APPENDIX 2

DATAFORM

Name: \_\_\_\_\_ Status:  Married  Single

Age: \_\_\_\_\_ Occupation \_\_\_\_\_

Age of Gestation: \_\_\_\_\_ OB score: G P ( )

Address: \_\_\_\_\_ Tel no: \_\_\_\_\_

Monthly income: \_\_\_\_\_

Level of education: \_\_\_\_\_

Duration of intake: \_\_\_\_\_ No of capsules taken: \_\_\_\_\_

Compliance complete:  yes  no

Noted side effects:  problems during delivery, if yes please specify \_\_\_\_\_

constipation

hypersensitivity reaction

others please specify \_\_\_\_\_

Type of Delivery: \_\_\_\_\_

Time of Delivery: \_\_\_\_\_

Expected Date of Confinement: \_\_\_\_\_

INSTRUCTIONS TO THE PATIENTS: Please fill-up the following information. If you have questions please ask. Whatever you write down will be strictly confidential.

*(Sagutan ang mga sumusuno na mga tanong. Ano man ang inyong isulat ay hindi isisiwalat ng walang pahintulot.)*

A. Onset of first drop of breastmilk. *(Oras unang napansin na may gatas sa suso).*

Time: \_\_\_\_\_ Date: \_\_\_\_\_



B. Amount of breastmilk produced. (*Dami ng gatas na nakuha*).


**APPENDIX 3**

**LIST OF FOOD AND DRUGS NOT TO BE TAKEN DURING THE STUDY**

*(Mga pagkain at gamot na bawal kainin)*

**Malunggay**

**Domperidone**

**Metoclopramide**

APPENDIX 4

A. Onset of breastmilk production

PATIENT NO	TIME OF ONSET (hr)	
	PLACEBO GROUP	MALUNGGAY GROUP
1	>48	6
2	42	18
3	6	6
4	18	6
5	>48	18
6	26	0
7	6	6
8	6	10
9	6	10
10	6	>48
11	32	>48
12	>48	14
13	10	22
14	10	0
15	>48	42
16	>48	>48
17	14	14
18	10	18
19	18	0
20	6	0
21	>48	22
22	>48	6
23	42	18
24	6	0
25	18	6
26	>48	18