Double-blind clinical trial to test the effectiveness of a mix of "Lavender Sp. and soy beans " in the increase of prolactin levels in blood.

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Summary

The following study aims to measure changes in prolactin levels in the blood of women with no or little production of breast milk that consumed this herbal and seed infusion mix over a given period.

A group of thirty female volunteer nursing patients were employed for the study, in order to perform the analysis of this infusion mix effectiveness.

50% of the patients (control subgroup) were given the infusion; 3 times daily for 16 days and the other 50% (intervention subgroup) were given a placebo infusion 3 times a day for the same period. We found that all patients who received the infusion experienced a 36% average increase of prolactin levels in their blood, while in the intervention group (who ingested placebo), only three patients showed 4.8% increase in prolactin levels in their blood, the other women in this group presented a decrease of 30.4%.

Keywords: herbal and seed mix, prolactin in blood, breast-feeding.

Introduction.

Lavender Sp. and soy bean infusion mix is a natural breastfeeding inducer recognized in Central America which is accepted and recommended by the medical community, due to the effectiveness and safety demonstrated in the induction of lactation in mothers with difficulty in breastfeeding their babies.

The trial was conducted by Dr. Gonzalo Prado Carranza et al. a doctor approved by the National Council of Science and Technology (CONACYT) in Mexico for clinical trials, with registration number 2009/11831.

Background:

1.- An increase in the incidence of cesarean sections in women at the time of delivery has been observed and it was also observed that this group of women had difficulty starting breastfeeding after childbirth, this is because the natural birth process, which activates the production of hormones prolactin and oxytocin responsible for lactation, was stopped. Prolactin is the hormone responsible for milk production, and oxytocin is responsible for uterine contractions and also for mammary contraction for the proper excretion of colostrum and maternal milk flow.

2.- In the field of observation it is also worth noting that women who experienced spontaneous or eutocic deliveries also have difficulty breastfeeding due to poor nipple stimulation or to stress as a result of the pace of modern life.

3.- This infusion mix is prescribed as a breastfeeding inducer / natural adjunct, because its mixture of Lavender Sp and Soy beans contains terpene and linalool oils; which when ingested by female post partum patients and / or lactating mothers, act by stimulating the pituitary, with the very satisfactory effect of releasing prolactin and oxytocin, without any side effects for either the mother or the baby, increasing milk production and facilitating its excretion.

Action Protocol:

Interdisciplinary team:

Control Doctor: Dr. Gonzalo Prado Carranza et al.

The Laboratory that performed the clinical analysis: Núcleo de Patología Clínica. (Guadalajara, Jalisco, México).

Sample.

A group of 30 volunteer female subjects in either a breast-feeding or postpartum stage were grouped as requested, to analyze the effectiveness of this infusion mix in the increase of the prolactin hormone in blood.

1. The initial group was broken up into 2 subgroups.

a) 15 patients in the CONTROL GROUP, between 20 and 35 years of age.
b) 15 patients in the INTERVENTION GROUP between 20 and 35 years of age.

2. Female subjects were selected in both groups, all with the following characteristics:

*Mexican
* Difficulty in breastfeeding
* Voluntary patients taken from a public hospital (Hospital General de Occidente, Zoquipan).

3. The control group was formed as follows:

Five female subjects between 20-25 years of age, of which three (3) have a history of cesarean section with an evolution of 3 to 30 days and 2 had a natural delivery with an evolution of 3 and 26 days.

Five female subjects between 26-30 years of age, all with a history of cesarean section with an evolution of 3 to 30 days.

Five female subjects between 31-35 years of age, with a history of natural childbirth, and four with a history of cesarean section with an evolution of 3 to 30 days.

Note:

The common denominator in the CONTROL sub-group is predetermined by the difficulty they all present in the production and excretion of breast milk.

4. The intervention group was comprised as follows:

Five female subjects between 20-25 years of age; of which 3 have a history of cesarean section with an evolution of 3 and 30 days and 2 females with a history of natural childbirth with an evolution of 5 and 18 days.

Five female subjects between 26-30 years of age, all with a history of cesarean sections with an evolution of 3 to 30 days.

Five female subjects between 31-35 years of age, with a history of natural childbirth and four females with a history of cesarean sections with an evolution of 3 to 30 days.

Note:

The "INTERVENTION" subgroup was comprised of women with similar characteristics to the ones in the “CONTROL” subgroup.

Method:

1.- Blood test samples were taken at the onset of the trial from the patients in both the control and intervention subgroups to measure their individual levels of prolactin in blood, as annexed in Appendix (A).

2.- The control subgroup was given an oral of this infusion mix, 3 times daily for 16 days (48 sachets in total) without interruption. These patients reported having taken one dose of this herbal infusion in the morning, another dose in the afternoon and the last dose in the evening, with no specific time schedule, only on the basis of the reference: morning, noon and night. Each dose was prepared at the time of consumption, only heating water and letting the envelope of this infusion rest in a cup (8 oz) for 5 minutes.

3.- The intervention subgroup was administered an oral infusion (placebo) based on Matricaria Chamomilla (chamomile) 3 times daily for 16 days (48 sachets in total) without interruption. These patients reported having taken one dose of Matricaria Chamomilla infusion in the morning, another dose in the afternoon and the last dose in the evening, with no specific time schedule, only on the basis of the reference: morning, noon and night. Each dose was prepared at the time of consumption, only heating water and letting the envelope of Matricaria Chamomilla rest in a (8 oz) cup for 5 minutes.

General recommendations given to patients subject to the double-blind trial:

Daily wash. (Full bath, clean nipple with cotton and water from a jug before breastfeeding the baby)

If nipples crack or if any skin discomfort appears in the area, please consult your doctor.

Drink the herbal 3 times daily for 16 days accompanied by plenty of liquids except alcohol.

Avoid intaking home remedies like brewer's yeast because it could skew the interpretation of results.

Keep a positive emotional and psychological predisposition to breastfeeding.

Breastfeed on demand (avoid meeting a fixed schedule during the 16 days this infusion intake, since it is very important to stimulate nipples.)

Stay as long as possible near the baby.

Do not consume any medications without first consulting your doctor.

Preferably use an adequate bra for breastfeeding.

Use clothing that facilitates breastfeeding at any time.

Massage breasts and nipples simulating drainage to avoid congestion in milk ducts.

Note:

The patients selected for the study were chosen to fulfill the following criteria:

All, patients without exception, wanted to breast-feed their children.

All patients breastfeed their babies at least 3 times a day to stimulate nipples.

All of them were made aware of the physical and psychological benefits for both mother and baby provided by the practice of breastfeeding.

None showed any sign or symptom or previous history of malnutrition, bulimia and / or anorexia.

None had inverted nipples.

None had a history of breast reduction surgery.

None reported being alcohol addicted or dependent.

None mentioned having a problem of substance abuse.

None had a history of pituitary adenoma.

None was currently pregnant.

None mentioned using medicines containing pargyline, hydrocodone, glucocorticoids and dopaminergic agonists such as bromocriptine.

None had a history of HIV. (AIDS).

They are all patients from the medium-low, medium, to medium-high social class.

All are Mexican nationals.

All were given a breastfeeding inducing package for 16 days (4 boxes with 12 sachets each) which together yielded an average intake of 48 envelopes.

Previous indications for blood sampling to determine prolactin levels:

Go to the appropriate laboratory without having eaten (at least 8 hrs.)

Be awake at least 2 hours before the extraction of the sample.

PROTOCOL FOR THE DOUBLE-BLIND TRIAL:

ELEMENTS INTERVENING IN THE DOUBLE BLIND TRIAL APPLIED TO: ***MIX OF LAVADER Sp. AND SOY.***	**BENEFITS FROM THE TRIAL.**
PARTICIPATING SUBJECTS • Control Group • Intervention Group	• Reduced likelihood of bias in the response to intervention. • Increased adherence to the established treatment and less likely to abandon the trial.
RESEARCHERS • Responsible for the design • Responsible for entering • Responsible for the intervention • Responsible for data collection • Responsible for awarding	• Less likely to transfer positive or negative attitudes to patients / subjects, in relation to the intervention being evaluated. • Less likely to use co-interventions (other interventions in addition to this study). • Less likely to remove patients away from the study or to adjust dose to patients in a differential manner. • Less likelihood of bias in the evaluation of intervention response, especially when it is subjective.
• Responsible for data analysis/evaluation, results	• Less likely to bias the assessment of the effects of the intervention being studied, especially when evaluating subjective effects.

Outcomes

The following double-blind trial was based on the comparison of 30 female patients, with the characteristics described above:

CONTROL SUB-GROUP						
Subjects between 20 and 25 years of age						
Age	Individuals	Delivery conditions	Days of evolution	Initial blood sampling to detect prolactin in blood	Final blood sampling to detect prolactin in blood	% of increase or decrease
20 to	1	Cesarean	3	180ng/ml	237.6ng/ml	+ 32 %
22 to	2	Cesarean	3	209ng/ml	296.78ng/ml	+ 42 %
22 to	3	Cesarean	30	198ng/ml	257.4ng/ml	+ 30 %5
24 to	4	Natural childbirth	3	203.4ng/ml	276.62ng/ml	+ 36 %
25 to	5	Natural childbirth	30	214.5ng/ml	304.59ng/ml	+ 42 %

	Subjects between 26 and 30 years of age					
Age	Individuals	Delivery conditions	Days of evolution	Initial blood sampling to detect prolactin in blood	Final blood sampling to detect prolactin in blood	% of increase or decrease
26 to	6	Cesarean	30	165.5ng/ml	226.73ng/ml	+ 37 %
28 to	7	Cesarean	3	124.3ng/ml	282.62ng/ml	+ 26 %
29 to	8	Cesarean	3	197.8ng/ml	276.92ng/ml	+ 40 %
27 to	9	Cesarean	30	202.4ng/ml	269.20ng/ml	+ 33 %
30 to	10	Cesarean	30	243.5ng/ml	328.72ng/ml	+ 35%

	Subjects between 31 and 35 years of age					
Age	Individuals	Delivery conditions	Days of evolution	Initial blood sampling to detect prolactin in blood	Final blood sampling to detect prolactin in blood	% of increase or decrease
31 to	11	Eutocic childbirth	3	117.4ng/ml	166.54ng/ml	+ 42 %
33 to	12	Cesarean	3	182.7ng/ml	252.12ng/ml	+ 38 %
34 to	13	Cesarean	30	230.46ng/ml	279.29ng/ml	+ 29 %
32 to	14	Cesarean	30	190.40ng/ml	266.56ng/ml	+ 40 %
35 to	15	Cesarean	30	84.20ng/ml	116.29ng/ml	+38 %

INTERVENTION SUB-GROUP						
Subjects between 20 and 25 years of age						
Age	Individuals	Delivery conditions	Days of evolution	Initial blood sampling to detect prolactin in blood	Final blood sampling to detect prolactin in blood	% of increase or decrease
23	1	Cesarean	3	193.4ng/ml	162.46ng/ml	- 16 %
23	2	Cesarean	30	201.6ng/ml	223.77ng/ml	+ 11 %
22	3	Cesarean	3	103.2ng/ml	108.36ng/ml	+ 05 %
20	4	Natural childbirth	5	230.1ng/ml	170.28ng/ml	- 26 %
25	5	Natural childbirth	18	190.3ng/ml	209.33ng/ml	+ 10 %

Subjects between 26 and 30 years of age						
Age	Individuals	Delivery conditions	Days of evolution	Initial blood sampling to detect prolactin in blood	Final blood sampling to detect prolactin in blood	% of increase or decrease
26	6	Cesarean	4	208.5ng/ml	154.29ng/ml	- 26 %
26	7	Cesarean	3	130.2ng/ml	91.14ng/ml	- 30 %
28	8	Cesarean	18	177.1ng/ml	187.72ng/ml	+ .06 %
29	9	Cesarean	30	204.7ng/ml	100.31ng/ml	- 51 %
30	10	Cesarean	3	143.3ng/ml	106.04ng/ml	- 26 %
Subjects between 31 and 35 years of age						
Age	Individuals	Delivery conditions	Days of evolution	Initial blood sampling to detect prolactin in blood	Final blood sampling to detect prolactin in blood	% of increase or decrease
32	11	Natural childbirth	3	96.7ng/ml	82.19ng/ml	- 15 %
34	12	Cesarean	3	108.4ng/ml	59.62ng/ml	- 45 %
35	13	Cesarean	3	153.2ng/ml	156.26ng/ml	+ .02 %
34	14	Cesarean	30	202.5ng/ml	137.70ng/ml	- 32 %
35	15	Cesarean	30	124.5ng/ml	90.89ng/ml	- 27 %

Conclusions:

The mix of lavender Sp. And soy beans infusion was tested in Mexican women of childbearing age with a health status acceptable under international health standards.

The groups selected for the double-blind trial were:

* Control Sub-group

* Intervention Sub-group

The control subgroup was monitored by administering 3 daily doses of this infusion mix during 16 days. Subjects were sampled to detect the levels of prolactin in their blood, first before taking an initial dose of the infusion and a final sample after completing the treatment.

Thus, it was verified through the laboratory analysis that this infusion is highly effective for the purpose it was created.

The control group increased by 36% averages THE LEVELS OF PROLACTIN IN BLOOD. This indicates that infusion mix, is highly recommended for women with either low milk production or difficulties with breastfeeding.

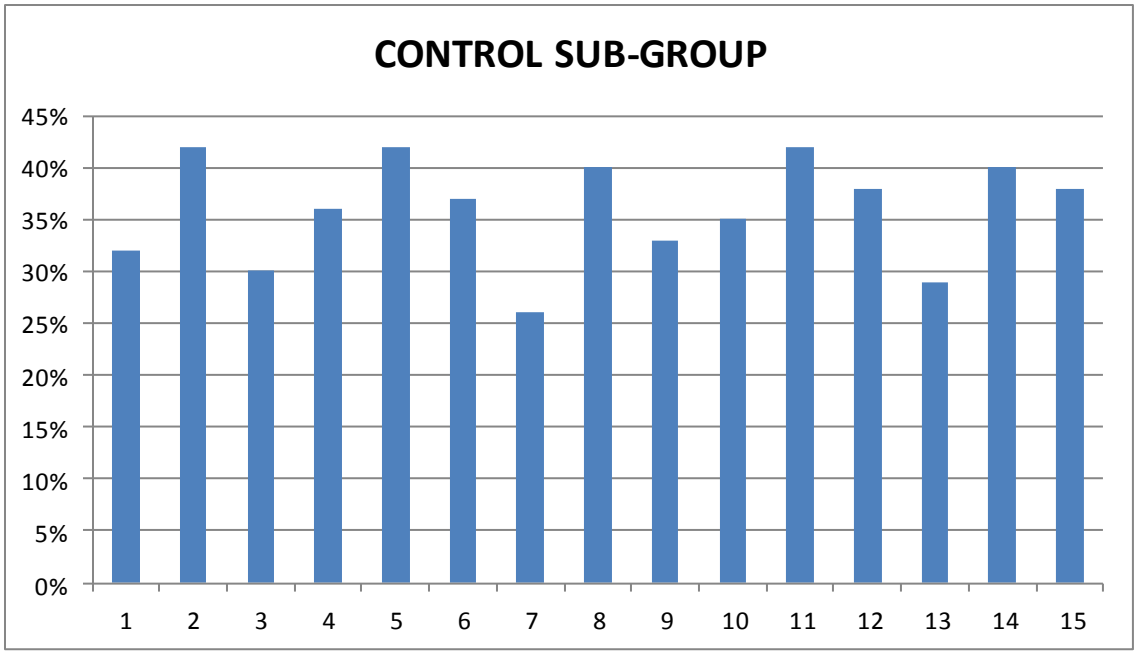
Participants in this group succeeded in nursing their babies, and therefore were generally pleased and more willing to continue breastfeeding their babies as long as possible.

By contrast, the intervention subgroup, that was administered an infusion of Matricaria Chamomilla as a placebo (the only variable in relation to the control group), SHOWED NO SIGNIFICANT INCREASE IN PROLACTIN LEVELS despite indications were given to the patients to succeed in breastfeeding their babies.

It is important to highlight the fact that the intervention group showed a reduction of 66% of prolactin levels in blood in the final sample compared to the first blood sample taken, and also reflected an average individual reduction of 30.4%. Mothers were quite frustrated because despite following the directions given and their motivation to successfully breastfeed their babies, they still had difficulty to feed their babies.

In general terms, with the intake of placebo there was an increase of prolactin in blood of 4.8% in 5 patients but the remaining patients experienced a decrease of 30.4%.

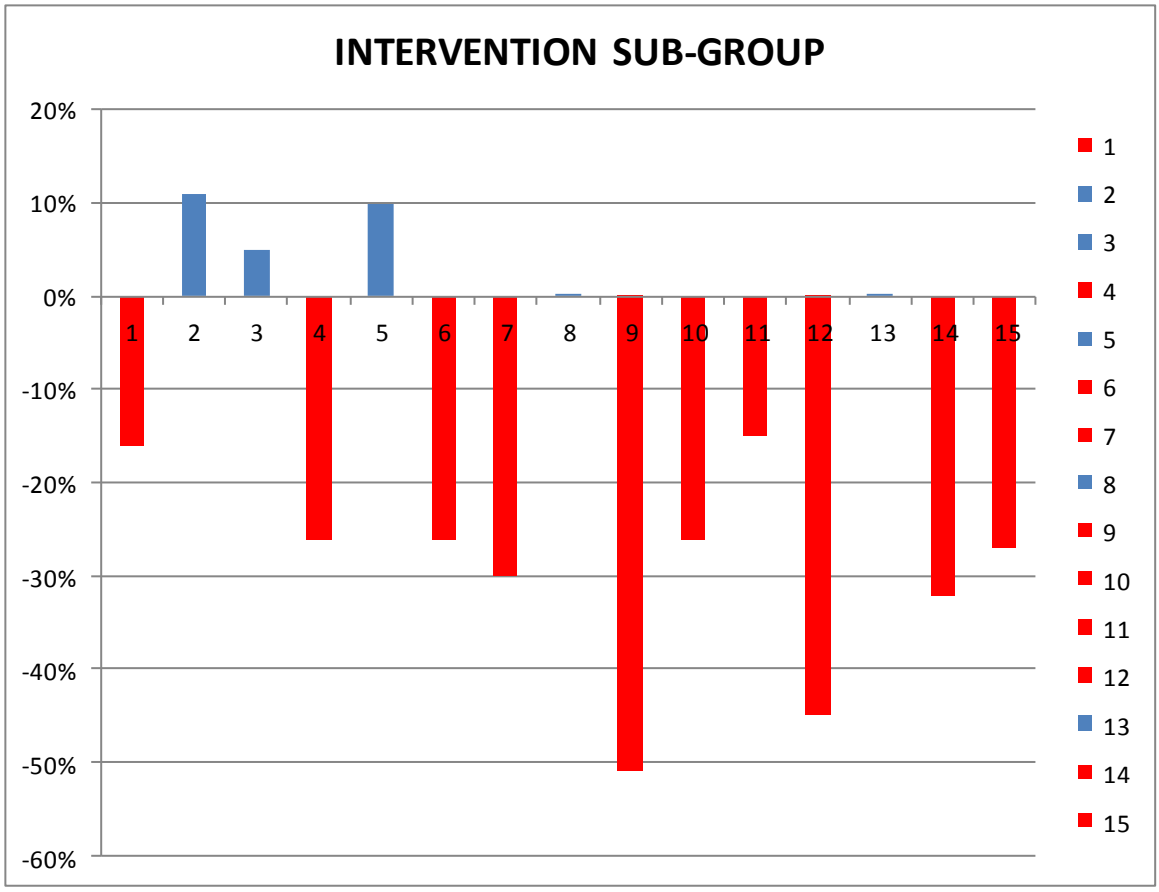
Graphic 1



Interpretation:

The study subjects from 20 to 25 years showed an average increase of 36.4% in prolactin within the first 16 days.
The study subjects from 26 to 30 years showed an average increase of 34.2% in prolactin within the first 16 days.
The study subjects from 31 to 35 years showed an average increase of 37.4% in prolactin within the first 16 days.
The total effect of increasing prolactin in blood in the control group was 36%.

Graphic 2



Interpretation:

Increase of prolactin in blood with placebo and nipple stimulation was 4.8%.
Reduction of Prolactin in the blood with placebo and nipple stimulation was 30.4%.