Ohhira – OMX Probiotics

(5 YEARS FERMENTATION)

Compilation of Abstract

OHHIRA Mountain Fruit Extract OMX PROBIOTICS CAPSULE "MAKES ME STRONGER"

- The Effect of OMX in the Treatment of Acute Non-bloody Diarrhea in Children.
- RCT on the Effect of OMX as adjunct in the Treatment of severe Pneumonia in Children
- The Effect of OMX on Immune Markers of Undernourished Filipino Children
- Beneficial Effect of OMX in Grade II Dengue Hemorrhagic Fever.
- The Effect of OMX as adjunct Treatment in Febrile Neutropenia in Children.
- OMX Probiotics vs. Nitrofurantoin in the prevention of Recurrent Urinary Tract Infection.
- Comparative study on OMX vs. Placebo in the Management of Dengue Hemorrhagic Fever between Grade I and II patients ages 5-18 years old.
- Randomized Clinical Trial in the Use of Probiotics; As an Adjunct Treatment for Neonatal Hyperbilirubinemia

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The Effect of Probiotic, Ohhira OMX Capsules, in the treatment of Acute Non-bloody DIARRHEA in infants 3-24 months of age

Author's: Hazel Valdoria, M.D., Felizardo Gatcheco, M.D.

ABSTRACT

BACKGROUND:

The term "probiotic" was first used to describe live microbial supplements which beneficially affect the host upon ingestion by improving the balance of the intestinal microflora. Probiotic bacteria favorably alter the intestinal microflora balance, inhibit the growth of harmful bacteria, promote good digestion, boost immune function, and increase resistance to infection. Their therapeutic use in diarrhea seems to be impressive. A number of agents have been isolated and studied with a view to clinical use.

OBJECTIVE: To determine the safety and efficacy of probiotics, Ohhira **OMX** Capsules, in the treatment of acute non-bloody diarrhea in patients 3-24 months of age.

DESIGN: Randomized clinical trial.

SETTING: A government secondary hospital in Metro Manila, Philippines.

SUBJECT: 70 infants 3-24 months of age with acute non-bloody diarrhea, with no to some dehydration, with no other concomitant illness and without any previous antimicrobial therapy: 35 (mean [+/-SD]) age 13.47 (+/-7.28) months in the intervention group and 35 (mean [+/-SD]) age 11.54 (+/-5.91) months in the control group.

METHODS: Subjects enrolled were randomized to either Oral Rehydration Salts (ORS) alone or ORS with Ohhira **OMX** probiotics, 1 capsule 2x a day for 5 days. The frequency, consistency and duration of diarrhea were then recorded in each group. T-tests, Mann Whitney U tests, Chi-square tests and Fischer Exact tests were used in the analysis of the different variables of both groups. Pvalue <0.05 was considered significant. The magnitude of the treatment effects (RR, RRR, ARR, and NNT) was also computed.

OUTCOME MEASURE: Number of days with diarrhea, decrease in the frequency of stool, change in the consistency of stool, weight gain, weight loss, recurrence of dehydration,occurrence of other diseases, occurrence of bloody diarrhea, and unplanned need for IVF.

RESULTS: Infants in Probiotic group had a shorter duration of diarrhea and decreased frequency of stool per day. The mean (SD) duration of diarrhea among the control group was 5.42+/-1.72 days compared to those given probiotics who had a mean SD duration of 3.17+/-1.34 days p-value=0.000001. On day of the trial, 74.3% of the probiotic group vs. 14.3% in the control group had a frequency of stooling of <3x/day. Both sets of patients did not manifest any adverse reactions. RR was 0.30, RRR was 0.70 and NNT was 1.67.

CONCLUSION: The use of probotics significantly affects the duration of diarrhea. The mean days were shorter 3.17 days in the probiotic group than in the non-probiotic group (5.42 days). Its use also produces no adverse effects.

Randomized Clinical Trial on the Effect of Probiotics, Ohhira OMX, as an adjunct Treatment of Severe Pneumonia in Patients 6-24 Months of Age

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ABSTRACT

OBJECTIVE: To determine the efficacy of a probiotic, **OMX** Ohhira capsules, as an adjunct in the treatment of severe pneumonia in patients 6-24 months old.

DESIGN: Randomized clinical trial.

SETTING: A government tertiary hospital in Manila, Philippines.

SUBJECT: 76 infants 6-24 months old with severe pneumonia, without previous antimicrobial therapy and no co-morbidities: 40 in the intervention group and 36 in the control group.

METHODS: Subjects enrolled were randomized to IV Ampicillin at 100mg/kg/day plus **OMX** Ohhira capsules 1 capsule 2x per day or IV Ampicillin alone. The duration of illness, previous treatment and illnesses, other signs and symptoms and vaccinations were recorded. Side effects were also noted. T test and Chi square test were used in the analysis of variables of both groups. All tests of significance were carried out at <0.05 level if significance and 95 % confidence interval. Risk assumptions were estimated using EPI info Stat Calc Version 2000. The magnitude of treatment Effects (RR, ARR, RRR, and NNT) were also computed. The outcome assessor was blinded as to the treatment groups.

OUTCOME MEASURE: Number of days with cough, tachypnea, retraction and fever, presence of hypoxemia, return to usual feeding, shift of IV antibiotic to oral preparation or another IV antibiotics, length of Hospital day and subgroup of patients without any other drugs taken previously.

RESULTS: Patients in the probiotic group had shorter duration of cough and hospital stay with Mean/SD 2.4+/-1 day compared to control with a mean/SD 4.3+/-1 day (p value <0.007). Resolution of tachypnea for age and retractions had a mean/SD 1.5+/-0.5 days in the intervention group compared to the control with mean/SD 4.3 +/-1 day (p value <0.001). Improvement of appetite had a mean/SD 1.0+/-0.2 day in the intervention group compared to the control with mean/SD 2+/-1 day (p value <0.001). On day 3 of the trial, 2 patients (5%) in the probiotic group compared to 17 patients (47%) were still tachypneic, with RR of 0.11, RRR of 0.89, ARR of 0.42 and NNT of 2. Only 1 patient (2%) in the treatment group had increased infiltrates on repeat CXR on day 3 of treatment compared to 13 patients (36%) in the control group. Shifting to another IV antibiotics was not statistically different.

CONCLUSION: The use of probiotics (**OMX Capsule**) significantly shortened the duration of cough and hospital stay even with no previous adjunct therapy (mean of 2.4 days in the treatment group vs. 4.3 days in the control group). Observable clinical significance had shorter mean day of onset of Resolution for tachypnea for age, cough, fever, rales, retractions, wheezing, improvement in appetite and shortened hospital stay among those given intravenous Ampicillin plus OMX capsules.

The Effect of Ohhira, OMX Probiotics Capsules on IMMUNE MARKERS of Undernourished Filipino Children

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ABSTRACT

OBJECTIVES: The study aims to determine whether probiotics can enhance the immunity of undernourished children by measuring changes in their (1) immune markers (CD3,CD4, CD8, CD19, CD 20, CD56), (2) weight and (3)incidence and duration of common infections, e.g., colds, pneumonia and diarrhea.

METHODS: Undernourished children were randomized into control and experimental group. Probiotics (mixture of Lactobacillus and Acidophilus) were given 2 times a day for eight weeks. Weekly weight, incidence and duration of illnesses recorded. Blood was drawn for immune markers before and after the study.

OBJECTIVES: The general objective of this study is to determine the effects of probiotics on the immune markers of undernourished Filipino children. The specific objectives are:

1) To describe the hematocrit level of undernourished children.
2) To determine the basal immunity markers - CD3, CD4, CD8, CD4:CD8,CD19, CD 20, CD56 of undernourished children.
3) To determine the degree of change in the immunity markers of undernourished children after intake of probiotics two times a day for 60 days as compared to those not given probiotics
4) To determine the incidence of common clinical infections (URI, diarrhea, pneumonia) between the probiotics and control group.

RESULTS: 29 children were enrolled, 14 in the control and 15 in experimental group. The probiotics group gained significant weight by 1 kg ($p<0.003$) . The basal levels CD3,CD4, CD8, CD19, CD 20, CD56 were normal in both groups. The control group showed an increase in CD4, CD8 levels compared to the probiotics group but both groups' levels stayed within normal limits . Although the incidence of illnesses was the same for both, there was significant shorter duration for the probiotics group. The median was 2 and 14 days for the probiotics and control group respectively ($p<0.001$).

CONCLUSION: Probiotics lead to significant weight gain. They also lead to shorter duration of infections. This current study has revealed that **OMX** probiotics have beneficial effects on undernourished children. Those children given probiotics have gained more weight. They also recover faster from their infections, the duration shorter, implying that there was enhancement of immunity.

The Beneficial Effect of Probiotics, Ohhira OMX Capsules in Grade II DENGUE Hemorrhagic Fever

Authors: Grace Uy, M.D., Felizardo Gatcheco, M.D., Luisito Ruiz, M.D.
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ABSTRACT

OBJECTIVE: To assess the clinical efficacy of oral intake of **OMX** Probiotics Capsule in pediatric patients with DHF Grade II

DESIGN: Prospective, randomized controlled trial, open label.

SETTING: A government-owned and controlled corporate hospital in Metro Manila

SUBJECT: 6 months to 18 years of age with diagnosis of DHF Grade II fulfilling World Health Organization criteria (Appendix), with the capacity to take oral medications, without known hypersensitivity to probiotics, with no presence of co morbidities (e.g. Pneumonia, diarrhea, etc.) at time of admission, with no presence of severe malnutrition as defined by Water low classification, with no presence of shock as defined by World Health Organization, and without concurrent intake of other medications not indicated for standard care of DHF.

METHODS: Patient's age, sexes were noted. Using table of random numbers, they were divided into control and experimental group. Eligible subjects in the experimental group were given **OMX** Probiotics capsules 1 capsule twice a day per orem.

RESULTS: 36 patients were enrolled in the study with 18 patients in the experimental and control groups, respectively. All patients were able to tolerate the **OMX** Probiotics capsule without any Problems. There was no significant difference in the proportion of males and females (p=0.17). There was a significant difference in the average temperature was achieved as shown by p values 0.04, 0.001 and 0.007 respectively. There was a significant difference noted in the experimental group only with p value=0.005. There was a marginally significant difference noted in the experimental group with p value=0.09. There was a significant difference noted in the control and experimental group with p values <0.0001 and 0.004 respectively. The mean day for the experimental group have normal HCT was significantly shorter than the control group (p=0.04) with a mean of 3.94 and 2.16 days for the control and experimental groups respectively. The mean day for the experimental group to have normal platelet count was significantly shorter than the control group (p=0.01) with a mean of 5.50 and 3.33 days for the control and experimental groups respectively.

CONCLUSION: This study has shown that patients with DHF Grade II given **OMX** Probiotics capsule did not progress to further deterioration of their condition and were able to have earlier normalization of their hematocrit and platelet count. The temperature also was noted to normalize earlier in the **OMX** Probiotics capsule group by about 2 days. This positive change could also lead to better clinical picture and signal slowing down of the inflammatory process. As to the effect on blood pressure, there was no significant effect by the use of probiotics.

In patients who present with DHF, the most feared sequel would be further plasma leakage and thrombocytopenia, which could lead to shock and death. Probiotics in this study have shown that it could reverse the trend by normalizing the hematocrit and increasing platelet count earlier, by 1.7 and 2.2 days respectively. Probiotics may stabilize the intestinal gut flora by halting the cytokine cascade through down regulation of the inflammatory cells and cytokines. It probably also control overgrowth of potentially pathogenic microorganisms with viral origin by antagonizing noxious or unwanted microorganisms, eliminate toxins and stimulate intestinal immune defense. We could therefore infer from this study that patients with Grade II DHF could benefit from probiotics early on their disease and that further progress to Grade 3 and 4 DHF could be prevented.

The Effect of OMX PROBIOTICS as adjunct treatment in FEBRILE NEUTROPENIA among children 2 -18 year old

Dra. Christine Natalita; Dra. Mary Ng Chua – Cardinal Santos Medical Center

ABSTRACT

DESIGN: A Double Blind, Placebo Controlled Randomized Clinical Trial

OBJECTIVES: To compare the proportion of patients with overall clinical improvement after a 7 day course of a probiotic (**Ohhira-OMX**) as adjunct treatment in children with febrile neutropenia.

STATISTICAL ANALYSIS: All analyses were done using the intention-to-treat principle, performed using STATA version 7. Descriptive statistics included mean and standard deviation for categorical data while percentage frequency distribution for categorical data. Tests of homogeneity of sample were done using Mann Whitney U test and Fisher Exact test when applicable. Comparison of outcomes between the two groups made use of Mann Whitney U Test for ranks (between groups comparison) and Wilcoxon Signed Ranks test for within groups comparison. Cox regression technique was used to determine the significant predictors of cure. Risk of treatment failure was defined as poor outcomes (no improvement in respiratory disease, diarrheal episodes) with values less than 1, falling within 95% confidence estimates as treatment success while values > 1 as treatment failure. (See below).

$$\text{Relative Risk} = \frac{\text{No. of adverse events in the treatment arm/total randomized to treatment arm}}{\text{No. of adverse events in the control arm/total randomized to control arm}}$$

All tests of significance were carried out at .05 alpha level of significance, 95% confidence interval.

RESULTS: A total of 42 episodes of febrile neutropenia were included in the final analysis. This sample size was sufficient to detect study a power of 80 % at 0.05 alpha level of significance and a type II error rate of 20%. A total of 18 (43%) subjects were randomized to take two tablets of probiotics (**OMX-Ohhira**) for 7 days while 24 (57%) were randomized to placebo. There was no statistically significant difference in terms of the mean age (5.8 vs. 6.8 years, p=.23); those given granulocyte colony stimulating factor (67% vs 63%, p=.78;); hematologic diagnosis (p=.19), chemotherapeutic regimens employed (p=.78); the antibiotics employed (p=.52); the baseline absolute neutrophil count (p=.39); highest temperature recorded (p=.79); the percentage positive yield of blood, urine and stool cultures (p=.19, p=.08, p=.07 - respectively).

CONCLUSION: Probiotic (**Ohhira-OMX**) produced clinical reduction in mean body temperature however, in this study; it failed to show a statistically significant increase in ANC when compared with placebo. With the use of probiotic (**Ohhira-OMX**) there was no statistically significance beneficial effects seen with other associated infections such as UTI, mucositis, respiratory infection and diarrhea episodes. There was shorter duration hospital stay in probiotics group and it was well tolerated without any adverse effects.

OMX Probiotics VS. Nitrofurantoin in the Prevention of Recurrent Urinary Tract Infection in CHILDREN

Dra. Rachelle Dela Cruz; Philippine Childrens Medical Center

ABSTRACT

OBJECTIVE: To compare the effectiveness of **OMX** Probiotics Capsule and Nitrofurantoin (NFN) in the prevention of RUTI in children with urinary tract abnormalities.

SPECIFIC OBJECTIVE

A. To compare the incidence and number of recurrences of infection while on **OMX** probiotics and Nitrofurantoin.
B. To determine the presence of bacteriuria by doing urine culture while on **OMX** Probiotics and Nitrofurantoin.
C. To compare the incidence of side effects of **OMX** Probiotics and Nitrofurantoin.

METHODS: The subjects were grouped into two. Group A (n=28) was given four months treatment with NFN at 1-2 mg/kg/day OD at bedtime. Group B (n=28) was given **OMX** Probiotics capsule (each containing approximately 59 million of 12 different strains of lactic acid bacteria including *Lactobacillus acidophilus, Lactobacillus rhamnosus* and *Lactobacillus fermentum*), 2 capsules daily in the morning on an empty stomach for 4 months.

Each patient had a detailed physical examination including a urine culture and sensitivity every month for 4 months. The diagnosis of UTI was based on clinical and laboratory findings. A urine culture was done whenever UTI is suspected during each monthly visit or in between visits. Based on the inclusion and exclusion criteria, a total of 70 patients were initially included in this prospective randomized controlled trial. The sample size of 70 was adjusted from the original calculated sample size of 56 subjects to provide replacement for possible drop-out cases (20%) for testing equivalency at α=0.05 and power=80%. 35 patients were randomized to Group A (NFN group) and 35 patients were randomized to Group B (OMX Probiotics group). The mean age of the sample population is 4.78 years with standard deviation of 3.60. The ages range from 0.25 yr (4 months) to 10 yrs/old. The mean age of Group A is 4.65±3.66 years. The mean age of Group B is 4.91±3.59 years.

RESULTS: During the course of the study, 16/28 (57.1%) patients in Group A while 14/28 (50%) patients in Group B had significant bacteriuria. There is no statistical difference in the incidence of significant bacteriuria in between the two groups, with p=0.592. Likewise, in terms of each monthly monitoring, using pearson chi-square test, there is no statistical difference in the proportions of significant bacteriuria between Group A and Group B thus, two groups are comparable in terms of each monthly monitoring. The mean number of significant bacteriuria after 4 months of monitoring in Group A is 1.46 whereas the mean number of significant bacteriuria after 4 months of monitoring in Group B is 1.32. Using student's t-test, there is no statistical difference in the mean number of significant bacteriuria between the two groups after 4 monitoring, with p=0.733. The two groups are comparable in terms of significant bacteriuria. Frequency of UTI shows a clinical trend towards a reduction in its incidence in Group B with overall incidence of UTI at 28.6% (8/28) in Group A versus 10.7% (3/28) in Group B however was not significantly different, with p value of 0.093. The two groups are comparable in terms of each monthly monitoring. The mean number of UTI recurrence after 4 months of monitoring in Group A is 0.39 whereas the mean number UTI recurrence after 4 months of monitoring in Group B is 0.14

CONCLUSION: This is the first randomized controlled study to show the role of **OMX** probiotics for preventing recurrent UTI in children with urinary tract abnormalities. Probiotics prophylaxis was as effective as antibiotic prophylaxis in children with urinary tract abnormalities. Side effects were statistically significant between groups with development and persistence of increased appetite and pasty stools as featured in majority of patients who received probiotics.

A Comparative Study on the Effects of Probiotics vs Placebo in the Management of Dengue Hemorrhagic Fever (DHF) Between Grade I and II on Pediatric Patients Ages 5 to 18 Years Old

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#Dr. Muneaki Takahata, Ph.D – co-Author.
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ABSTRACT

OBJECTIVE of the Study: The general objective of the study is to be able to compare the effects of probiotics (OMX) versus the placebo in course of DHF.

DESIGN: Non Randomized Single Blinded Placebo Controlled Trial

SETTING: A Private Tertiary Medical Center in Urban Philippines

PARTICIPANTS: Children aged 4 – 18 years old admitted with a diagnosis of Dengue Hemorrhagic Fever Grade I and Grade II after a standard clinical evaluation. Thirty six children were randomized into placebo group and probiotic group.

INTERVENTION: The subjects were given one probiotics capsule or placebo twice daily during the treatment course. Intravenous fluids and antipyretics were administered as the standard treatment protocol.

MAIN OUTCOME MEASURES: The following clinical parameters were compared: resolution of fever, return of appetite, occurrence of bleeding, abdominal pain and Hermann's rash. Complete blood count was extracted daily and the following were compared: hematocrit and platelet count.

RESULTS: A total of 36 children were evaluated in the study. Twenty four were given OMX and twelve were given placebo. Subjects, who received probiotics showed significant improvement from symptoms such as fever resolution, return of appetite and appearance of Hermann's rash. Platelet count was noted having a rapid increase in trend among the probiotics rather than placebo.

CONCLUSION: Probiotics proved to increase the platelet count of the twenty four patients who took it. The symptomatology results also showed potential improvement in fever resolution as well as return of appetite for patients given probiotics.

Randomized Clinical Trial in the Use of Probiotics; As an Adjunct Treatment for Neonatal Hyperbilirubinemia

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ABSTRACT

OBJECTIVE: To determine the efficacy of a probiotic. Omx Ohhira capsules as an adjunct treatment of Neonatal Hyperbilirubinemia.

DESIGN: Randomized Control Clinical Trial

SUBJECTS: 59 Normal full term neonates, candidate for phototherapy and not in any antibiotic treatment regimen.

METHODS: Subjects who complied with the inclusion criteria were ramdomized into two groups. 1. Phototherapy group alon, 2. Phototherapy with OMX Group. Bilirubin were collected from all the subjects.

OUTCOME MEASUREMENTS: Biliribin assay were taken prior to exposure to phototheraphy. After 24 to 48 hours of exposure; length of hospital stay.

TABLE 1. MEAN (STD. DEV.) TOTAL BILIRUBIN LEVEL BEFORE, AFTER 24 HOURS AND 48 HOURS OF EXPOSURE AMONG NEONATES WITH OMX AND WITHOUT OMX.

	TB before Exposure	TB after 24 hours of exposure	TB after 28 hours of exposure
With OMX	13.99 (±4.55)	11.82 (±4.26)	11.82 (±4.26)
Without OMX	12.41 (±2.99)	11.74 (±2.82)	11.74 (±2.82)
Man-Whitney p-value	0.1498	<0.0001	<0.0001

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