Attachment 1. (9.9)

Date _____

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. M.R. Islam

Trainee Investigator (if any) _____

Application No. 82-007

Supporting Agency (if Non-ICDDR,B) _____

Title of Study Comparative studies of oral Rehydration solutions in childhood diarrhoea - Potassium 30 m.mols vs 20m.mols and Base 30 m.mols vs no base.

Project status:
(✓) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA).

1. Source of Population:
   (a) Ill subjects (Yes) No
   (b) Non-ill subjects Yes (No)
   (c) Minors or persons under guardianship (Yes) No
2. Does the study involve:
   (a) Physical risks to the subjects (Yes) No
   (b) Social Risks Yes (No)
   (c) Psychological risks to subjects Yes (No)
   (d) Discomfort to subjects (Yes) No
   (e) Invasion of privacy Yes (No)
   (f) Disclosure of information damaging to subject or others Yes (No)
3. Does the study involve:
   (a) Use of records, (hospital, medical, death, birth or other) (Yes) No
   (b) Use of fetal tissue or abortus Yes (No)
   (c) Use of organs or body fluids (Yes) No
4. Are subjects clearly informed about:
   (a) Nature and purposes of study (Yes) No
   (b) Procedures to be followed including alternatives used (Yes) No
   (c) Physical risks (Yes) No
   (d) Sensitive questions Yes (No)
   (e) Benefits to be derived (Yes) No
   (f) Right to refuse to participate or to withdraw from study (Yes) No
   (g) Confidential handling of data (Yes) No
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure (Yes) No
5. Will signed consent form be required:
   (a) From subjects Yes (No)
   (b) From parent or guardian (if subjects are minors) (Yes) No
6. Will precautions be taken to protect anonymity of subjects (Yes) No
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
   ✓ Protocol (Required)
   ✓ Abstract Summary (Required)
   ✓ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
   ___ Informed consent form for subjects
   ✓ Informed consent form for parent or guardian
   ___ Procedure for maintaining confidentiality
   ___ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

R. Islam
Principal Investigator

RECEIVED 10 AUG 1999

Trainee

SECTION I - RESEARCH PROTOCOL

1. TITLE: COMPARATIVE STUDIES OF ORAL REHYDRATION SOLUTIONS IN CHILDHOOD DIARRHOEA - POTASSIUM 30 M.MOLS VS 20 M.MOLS AND BASE 30 M.MOLS VS NO BASE.

2. PRINCIPAL INVESTIGATOR: Dr. M. R. Islam

   CO-INVESTIGATORS: Dr. P. K. Bardhan, Dr. Masud Ahmed, Mr. Akbar Ali.

   CONSULTANT: Dr. T. Butler

3. STARTING DATE: March, 1982

4. COMPLETION DATE: August, 1982

5. TOTAL INCREMENTAL COST: $ 5108

6. SCIENTIFIC PROGRAMME HEAD: This protocol has been approved by the Pathogenesis and Therapy Working Group.

Signature of Scientific Programme Head: Thomas Butler

Date: Jan 26, 1982

7. ABSTRACT SUMMARY:

A clinical trial is proposed to compare the effectiveness and safety of three types of oral rehydration solutions in the treatment of childhood diarrhoea. One group will receive high (30 mmols/L) potassium available from potassium citrate which will be used alone in place of sodium bicarbonate and potassium chloride, components of WHO recommended ORS. Another group will receive widely used WHO recommended ORS (containing 20 mmols of K^+/L) and the third group will receive ORS without base. Each group will comprise 50 comparable children under 5 years of age & developed moderate degree of dehydration (according to WHO criteria). These children will be treated with oral therapy alone. Selection and treatment of patients will be done in double blind random way. Intake and output, biochemical changes specially potassium and bicarbonate, degree of anorexia will be compared at 0, 24 and 48 hours of oral treatment in these three groups. Nutritional status of these children using height and weight will also be compared. It is expected that i) children will be benefited by increased amount of potassium in ORS and ii) may not require base in ORS particularly when suffering from rotavirus diarrhoea where bicarbonate loss in stool is minimal.

8. REVIEWS:

(a) Research involving human subjects: _____

(b) Research Committee: _____

(c) Director: _____

(d) BMRC: _____

(e) Controller/Administrator: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective:

The objective of this study is to compare the effectiveness and safety of three types of oral rehydration solutions;

a) whether potassium citrate alone is an adequate ingredient in place of potassium chloride and sodium bicarbonate; thus reducing the number of ingredients of ORS from four to three.

b) whether increased concentration of potassium from 20 m.mols to 30 m.mols/litre of ORS will provide more benefit to the patients particularly the undernourished children.

c) whether rotavirus diarrhoea can be managed with ORS without base.

2. Background:

It is well known for a long time that there are losses of water as well as electrolytes in acute watery diarrhoea caused by Vibrio cholerae (1). Recently Molla et al have studied the stool electrolyte contents of acute watery diarrhoeas of children under 5 years of age suffering from diarrhoea due to V. cholerae, ETEC & rotavirus (2). They observed that children looses more than 30 m.mols potassium/L in these three types of diarrhoeas (cholera 30, ETEC-37 and rotaviurs 38 m.mols/L), where as CO_2 content of rotavirus diarrhoeal stool was found to be minimal, 7 m.mols/L as compared to E. coli 18 m.mols/L & cholera 32 m.mols/L (2). These three agents are responsible for most

of the endemic diarrhoeas among children under 5 years age in many developing countries and two (except cholera) are present even in developed countries. WHO recommended oral rehydration solution contains only 20 m.mols of K^+/L which is not adequate enough to replace the loss in diarrhoea stool (3).

Most children in developing countries are suffering from some degree of malnutrition and depletion of total body potassium. From potassium balance study in Jamaica by Nalin & co-workers it was confirmed that infants required significantly more potassium than adults to replace their losses in diarrhoea, and indicated that hypokalaemia can be eleminated by using 35 m.mols of K^+/L in the oral rehydration solution. They observed that net K^+ absorption at 24 hrs was more than twice as high in the high potassium (35 m.mols/L) group than the low potassium (20 m.mols) group. None of the infants receiving high potassium had developed hyperkalaemia or hypokalaemia at 6 or 24 hrs of oral therapy. In contrast, hypokalaemia (average 3.06 ± 0.04 m.mols/L) was observed at 24 hrs in about 19% children receiving 20 m.mols of K^+/L. Hypokalaemia persisted in 5 out of 19 infants even after one week (4). The significance of this findings could be appreciated by considering the fate of infants in areas where diarrhoea is hyperendemic, who may have six or more attacks per year. Repeated therapy of such infants with oral solutions containing inadequate or no potassium will certainly increase the risk of significant total body potassium depletion during serial diarrhoeal attacks with associated risk of the development of symptoms of hypokalaemia. Thus they felt that there is a great need

to consider the possibility of raising the K^+ concentration of ORS above 20 m.mols/L (4). Moreover 25 m.mols of K/L of ORS had previously been used in ICDDR,B for older children and adults (5). Same type of suggestions came even from World Health Organization. This organization also think that fluid containing 25 m.mols of K^+/L of ORS are safe, effective and produces a positive potassium balance in all age groups. One disadvantage of increasing potassium concentration is that such solutions may irritate the gastric mucosa and may have an unacceptably bitter taste particularly when potassium chloride had been used (6). Taste of potassium citrate is much better than potassium chloride and thus hoped to be well accepted by the sick children.

The only report came from Kahn and Blum of Belgium published as a letter in Lancet regarding hyperkalaemia with WHO recommended ORS. They have observed potassium concentration of serum on admission 4.1 m.mols/L rose to 6.1 m.mols/L after 24 hours of oral therapy on 7 well nourished Belgian children (7). They felt that for well nourished children under one year of age, treatment with UNICEF/WHO type ORS containing 20 m.mols of K/L should not last for more than 24 hours. After that time monitoring of plasma K^+ level would be needed. Of course those infants were not breast fed. These types of observations have not been reported from any developing countries where most children are under-nourished with diminished reserve in total body potassium.

A comparative clinical trial using base precursors like acetate and citrate in place of bicarbonate in the ORS by Islam & Coworkers at ICDDR,B has shown that these base precursors are quite effective for the correction of acidosis (8). Patients, both adults and children, admitted with moderate dehydration and acidosis (serum bicarbonate level less than 16 m.mols) on admission were rehydrated and their acidosis corrected equally in all three groups (acetate, citrate & bicarbonate) within 24 hours of oral therapy (8). Citrate had also been used before either alone (9) or in combination with bicarbonate in various concentrations in the oral rehydration solutions with success (5).

There is widespread agreement that complete formula such as that recommended by WHO, including both potassium and bicarbonate, is the best formulation for rehydration of dehydrated children. But there is also a place for home-mixed sugar and salt solution that can be prepared any where when prepackaged complete formulation are not available. With respect to effectiveness, studies in Hondurus and Bangladesh suggest that sugar and salt formula is effective for rehydration (10,11). In the Hondurus study acidosis was not found to be a problem but on the other hand potassium deficiency did occur. More than twice as many of the Honduran children receiving sugar and salt developed abnormally low potassium levels as did those receiving complete formula (10). Probably these children had suffered from Rotavirus diarrhoea where bicarbonate loss is minimum and thus could be treated without bicarbonate containing ORS. The amount of bicarbonate loss in stool in Rotavirus infection (7 m.mols/L) could be handled by the lungs and kidneys.

The present WHO recommended ORS packet contains bicarbonate which have short shelf life as the ingredients form lump in humid condition. This is the most single important disavantage of the present WHO/UNICEF packets. If ORS without base is found to be harmless in the treatment of infantile diarrhoea, it will not only reduce the cost of ORS but also prolong its shelf life.

We share the same view expressed by Jahn Trip and John Harris that Oral rehydration solution should be formulated to meet the demands of the locality in which it will be used taking account of the prevalent electrolyte disturbance, age, nutritional status of the patients and etiological agents of diarrhoea in the locality (12).

3. Rationale:

(a) Base precursor salts acetate and citrate are stable salts and have been found quite effective for correction of acidosis when given orally.

(b) Studies in developing countries have shown that WHO recommended ORS containing 20 m.mols of K^+/L is not adequate for correction and maintenance of potassium balance in paediatric diarrhoea.

(c) If potassium citrate can be used in place of sodium bicarbonate and potassium chloride then the number of ingredients will be reduced from four to three as potassium citrate alone will provide both potassium as well as required base used in ORS.

(d) Oral rehydration solution without base may be adequate in the treatment of rotavirus diarrhoea of infants since bicarbonate loss is minimal in their stool. This will not only reduce that cost but also prolong the shelf life of ORS packets.

COMPOSITION OF ORAL REHYDRATION FLUIDS TO BE USED IN CLINICAL TRIAL

Grams/L

	Nacl	Kcl	$NaHCO_3$	Pot.citrate	Glucose
1. ORS without base	5.3	1.5	0	0	20
2. WHO ORS	3.5	1.5	2.5	0	20
3. ORS with High K^+	5.3	0	0	3.24	20

m.mols/L

	Na^+	K^+	HCO_3^-	Cl^-	Glucose
1. ORS without base	90	20	0	110	111
2. WHO ORS	90	20	30	80	111
3. ORS with high K^+	90	30	30	90	111

B. Specific Aims:

1. To compare the effectiveness of WHO recommended oral rehydration solution containg 20 m.mols of K^+ per litre with that of the proposed solution containg 30 m.mols/L for correction and maintenance of hypokalaemia in pediatric diarrhoea.

2. To compare the safety and effectiveness of oral rehydration solution without any base in Rotavirus diarrhoea.

METHODS AND PROCEDURE:

1. Subjects:

150 patients <5 yrs of age with history of acute watery diarrhoea of less than 24 hours duration and clinically considered moderately dehydrated (13) will be selected for the study. Patients will be excluded from the study if they have received any antibiotics within a week prior to hospitalization. Children suffering from other complications and severe malnutrition will also be excluded from the study. Patients will be selected each morning with the first 3 children (6 months - 5 years of age) fulfilling the above criteria. Their legal guardians will be inmormed of the study and if thcy agree to participate, they will be included in the study.

2. Randomization of patients:

Patients will be randomised to one of the 3 group by choosing a slip of paper from an envelop. This paper will contain one of the 6 letters (A,B,C.D,E,F), 2 of these will contain one of the 3 oral solutions under study.

3. Clinical Procedures:

Selected patients will be admitted directly in the study ward. After randomization as described above, the following procedures will be followed until diarrhoea stopped.

(a) Body weight will be taken on admission & subsequently every 8 hourly.

(b) Clinical history of illness and thorough physical examinations on admission.

(c) Vital signs (P/T/R) on admission and every 4 hourly.

(d) Hydration status and clinical assessment will carefully be done every 4 hourly.

(e) 2 c.c. venous blood will be drawn for Hct, electrolytes & specific gravity on admission, after 24 hours and 48 hours, if diarrhoea continues, then after 72 hours also.

(f) Blood urea will be done from the same blood on admission & after 24 hours.

(g) Catheter specimen of stool will be sent for Dark field examination for V. cholerae and culture in all plates for enteropathogens including E. coli, shigella and salmonella etc. Stool will be saved for rotavirus detection by ELISA technique.

No intravenous fluid will be administered. Initial rehydration as well as subsequent maintenance of hydration will be done with only one of the three oral solutions alone.

Only dark field positive cases will be treated with Tetracycline (125 - 250 mgm every 6 hourly) for 2 days only. Furazolidine may also be used instead of Tetracycline.

Urine will be collected in PUC bags for measurement of urinary potassium at 24, 48 and 72 hours.

Patients will be given oral fluid ad libitum to drink as long as diarrhoea continues. Free water and diet will be allowed without any restriction.

A summary of clinical measurements is as follows:

	Adm	4 hrs	8 hrs	16 hrs	24 hrs	48hrs	72 hrs
Cl. evaluation	✓	✓	✓	✓	✓	✓	✓
HCT & Sp. Gr.	✓	—	—	—	✓	✓	✓
Serum Electrolytes	✓	—	—	—	✓	✓	✓
Urinary potassium	—	—	—	—	✓	✓	✓
Weight	✓	—	✓	—	✓	✓	✓
Intake	✓	—	✓	✓	✓	✓	✓
Output	✓	—	✓	✓	✓	✓	✓

The clinical evaluation will include examinations for skin turgor, mucous membrane, Eye signs, pulse volume, B.P., Weight, urination and signs of pulmonary oedema etc. Patients will be under constant observation in the study ward. Special attention will be given for the appearance of any basal crepitations as a complication of pulmonary edema, such cases will be excluded from the study and appropriate treatment will be provided.

Failure of the therapy will be defined as the inability to rehydrate, maintain hydration or failure to correct electrolyte imbalance. Oral therapy failure to rehydrate initial fluid loss or to maintain hydration based on clinical and laboratory signs e.g. rise in HCT and plasma Sp. gravity more than 1030, fall in body weight and development of signs and symptoms of

electrolyte imbalance including pulmonary edema due to acidosis, severe lethargy or paralytic ileus for hypokalaemia, restlessness or irritability for hyperkalaemia, etc. if developed during the oral therapy study period will be considered as a treatment failure. Oral therapy treatment failure cases will be treated with appropriate intravenous solutions.

4. Analysis of Data:

All the informations will be kept in a flow sheet for each patient. Analysis will be straight forward. Admission weight, plasma specific gravity, and electrolytes (Na^+, K^+, Cl & TCO_2) will be compared with that of 24 hr, 48 hr and discharge values. Tests will be done for statistical significance (student's t test). Also the amount of oral fluid taken and its correlation with correction of hypokalaemia and acidosis will be compared keeping WHO recommended fluid as standard.

D. SIGNIFICANCE : From the result of this study, it will be possible to determine whether a solution containing higher concentration of potassium is better than WHO/UNICEF recommended ORS for correction of hypokalaemia resulting from repeated attacks of diarrhoea in Bangladeshi children under 5 years of age. Also it will be possible to postulate from this study that ORS without base may be adequate in the treatment of rotavirus diarrhoea.

E. FACILITIES REQUIRED

i) No new office space is required.

ii) Laboratory facilities for routine Microbiology, Biochemistry, Clinical Pathology will be utilized.

iii) Hospital Resources - the study ward will be used and on average 3 patients are needed per day. Thus a total of 9 beds will be sufficient.

iv) Animal Resources will be needed for E. coli study.

F. COLLABORATIVE ARRANGEMENT - Nil.

SECTION III - BUDGET

DETAILED BUDGET

1. Personnel Services

Name	Position	% of effort	Project Requirements Taka	Dollar
Dr. M.R. Islam	- Principal Investigator	25%	13000	-
Dr. H.K. Bardhan	- Co-Investigator	15%	4000	-
Dr. Masud Ahmed	- Clinical Research Fellow	25%	5000	-
Mr. Akbar Ali	- Head, Bio-chemistry	10%	3000	-
Dr. T. Butler	- Consultant	-		-
3 Senior Staff Nurse		25%	7000	-
3 cleaners		25%	3000	-
1 Study Clerk		25%	2000	-
Baeteriology technician		1 person month	3000	-
Biochemistry technician		1 person month	3000	-
Veterinarian			2000	-
			45000	-

	Taka	Dollar
2. Supplies & Materials:		
Stool culture x 150 specimens	3750	-
HcT & specific gravity x 350 specimen	700	-
Electrolytes, 450 specimen	5400	-
Urea X 300 specimen	1800	
Infant mouse assay 450 isolates	4500	-
ELISA test - 150 specimen	450	-
Glass ware, plastic	-	250
750 ORS packets (150x5) - Taka 2 per packet	1500	
	18100	250

3. Equipments - Nil

4. Hospitalization - 150 x 3days x Taka 150/day = 67500

5. Outpatient - Nil

6. Transport - Nil

7. Travel (International) - Nil

8. Transport of Things - Nil

9. Rent - Nil

10. Printing:	Forms	1000	-
	Publication	-	300

11. Contractual service - Nil

12. Construction - Nil

SECTION III - BUDGET

BUDGET SUMMARY		Taka	Dollar
1. Personnel	-	45000	-
2. Supplies	-	18100	250
3. Equipments	-	-	-
4. Hospitalization	-	67500	-
5. Outpatient	-	-	-
6. Transport	-	-	-
7. Travel	-	-	-
8. Transport of things	-	-	-
9. Rent	-	-	-
10. Printing	-	1000	300
11. Contractual Service	-	-	-
12. Construction	-	-	-
	Total	131600	550
	Incremental cost excluding personnel salary.	86600	550
	Total incremental cost	86600	550

Conversion rate $1 = Tk. 19

= $ 4558

Grand total = $ 5108

REFERENCES:

1. R.A. Phillips: Water and Electrolytes losses in cholera. Fed. Proc. 23:705, 1964.

2. Molla, A.M. et al: Stool Electrolyte content and purging rates in diarrhoea caused by Rotavirus, Enterotoxegenic E. coli & V. cholerae in children. J. Pediatrics. Vol. 98. No. 5 pp 835-838.

3. Clements, M.L. et al: Potassium Supplements for Oral Diarrhoea Regimens. Lancet Oct. 18, 1980, 854.

4. Nalin, D.R. et al: Comparison of Low and High Sodium and Potassium Content in Oral Rehydration Solutions. J. Pediatrics 97:5, Nov. 1980, 848-853.

5. Nalin, D.R. et al: Oral (Nasogastric) maintenance Therapy for Cholera in all age groups. Bull WHO. 43:361, 1970.

6. WHO/DDC/79.3, pp 5-21.

7. Kahn, A & Blum. D: Hyperkalaemia and UNICEF type rehydration solutions. Lancet, May 17, 1980.

8. Islam, M.R. et al: Use of base precursors as a substitute of bicarbonate in the oral rehydration solution (to be published).

9. Sunoto et al: Oral rehydration solution. An appropriate formula for acute Infantile Diarrhoea. Paediatricia Indonesiana 20, 205-215 Sept-Oct 1980.

10. Clements, M. et al. Comparison of Simple Sugar/salt versus glucose electrolyte oral rehydration solution in infant diarrhoea (1980) 12.p. unpublished.

11. Islam, M.R. et al: Laban-Gur (common salt and brown sugar) oral rehydration solution in the diarrhoea of adults. J. Trop Med & Hyg. 1980.

12. Tripp. J.H. & Harris JT - UNICEF/WHO glucose electrolyte solutions not always appropriate. Lancet (letter), Oct. 11, 1980.

13. A manual for the treatment of acute diarrhoea WHO/CDD/SER/80.2 pp 6.

ABSTRACT SUMMARY FOR ETHICAL REVIEW COMMITTEE

1. 150 patients below 5 years of age with history of acute watery diarrhoea of less than 24 hours duration and clinically considered moderately dehydrated,will be selected for the study. Children suffereing from other complications including severe malnutrition will be excluded from the study.

   Studies in developing countries have shown that WHO recommended ORS containing 20 m.mols of potassium/litre is not adequate for correction and maintenance of potassium balance in paediatric diarrhoea. This is particularly important for developing countries like Bangladesh, where diarrhoea is hyperendemic, and where the nutritional status of most of the children is below normal. Thus it has been felt that there is a great need to consider the possibility of raising the potassium concentration of ORS, specially treating children below 5 years of age.

   Rotavirus is the commonest cause for causing diarrhoea in children below 2 years of age. The amount of bicarbonate loss in stool in Rotavirus infection is small (about 7 m.mols/L) and could be handled by the lungs and kidneys. Thus ORS without any base may be adequate in the treatment of Rotavirus diarrhoea of infants. This will not only reduce the cost but also prolong the shelf life of ORS packets as bicarbonate form lump in humid condition.

2. There are no significant potential risks involved in this study.

3. Patients will be under constant observation, and appropriate treatment will be provided whenever any complication arises.

4. Only patient identification numbers will be used during analysis of results.

5. Signed consent will be obtained from the parents or legal guardians.

6. No special invertiew except simple clinical history will be necessary.

7. Patients will be potentially benefitted from this study. It is anticipated that increasing potassium concentration in the ORS will make it more effective for treatment of diarrhoea in children and will produce in positive potassium balance. Elimination of base from ORS will not only simplify and reduce the cost of ORS packets but will also increase the shelf life of ORS packets.

8. Hospital records and body fluids will be required.

CONSENT FORM

COMPARATIVE STUDIES OF ORAL REHYDRATION SOLUTION IN CHILDHOOD DIARRHOEA

STATEMENT TO BE READ TO THE GUARDIAN WHEN CONSENT IS OBTAINED

The ICDDR,B is carrying out research to develop most economic and effective way to treat diarrhoea in a simple way like, oral saline. We will be trying 3 kinds of oral solution to treat diarrhoea. They were found reasonably effective in previous studies without serious complications. We want to compare these 3 types of oral solutions to find out the best one. We would like you to participate in this study for the benefit of mankind. If you decide to participate in the study, you can expect that:

1. Your child will be given best possible care.

2. It will be necessary to stay for at least 2-3 days on even more until diarrhoea stops.

3. While your child will be in the hospital, we will test a total of 3 samples of blood (about 2-3 c.c. each time) to know the health position of your child. These will be routine tests.

4. If the oral saline given to your child fails to treat or causes any discomfort, you child will be taken off the study and will be treated with proper I.V. fluid.

If you do not participate in the study, still your child will be treated like other patients in this hospital. If you participate in the study, you will be at liberty to withdraw your child from the study without any obligation, and still yourchild will get proper treatment.

Understanding and realizing fully, if you are voluntarily willing to allow your child to participate in this study, then please sign your name or put your left thumb impression below.

_____
Investigator

Date: --------

_____
Signature or Left thumb impression of Legal Guardian.

Date: ----------

শিশুদের পেটের পীড়ায়
খাবার স্যালাইনের তুলনামূলক গবেষণা

সম্মতি পত্র

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র খাবার স্যালাইন দিয়ে কিভাবে অতি কম খরচে অথচ সকল ভাবে উদরাময় রোগের চিকিৎসা করা যায় তা নিয়ে গবেষণা চালিয়ে যাচ্ছে। বর্তমানে আমরা তিন প্রকার স্যালাইন দিয়ে উদরাময় রোগের চিকিৎসার গুনাগুন পরীক্ষা করতে যাচ্ছি। পূর্বেও এই তিন প্রকার খাবার স্যালাইন দিয়ে বিশ্বের অন্যান্য উদরাময় রোগের চিকিৎসা সম্ভব হয়েছে।

বর্তমান গবেষণা দ্বারা কোন রকম স্যালাইন তুলনামূলক ভাবে বেশী কার্যকরী তা নিরুপন করতে চেষ্টা করা হবে। মানব জাতীর কল্যাণ সাধনায় আশা করি আপনিও এই গবেষণায় অংশ গ্রহণ করতে রাজী হবেন।

আমাদের এই গবেষণায় অংশ গ্রহনে সহায়ক হলে নিম্নোক্ত ব্যবস্থাদি গ্রহণ করা হবে।

১। আপনার শিশুর উদরাময় রোগের চিকিৎসার সুব্যবস্থা হবে।

২। শিশুর পায়খানা ঠিক না হওয়া পর্যন্ত যত দিন অথবা প্রয়োজনে বেশী সময় হাসপাতালে থাকতে হবে।

৩। হাসপাতালে চিকিৎসা থাকা কালীন আপনার শিশুর শরীরের অবস্থা জানার জন্য প্রতিবার ২ সি সি করে মোট ৩ বার রক্ত পরীক্ষার প্রয়োজন হবে।

৪। এই খাবার স্যালাইন দিয়ে আপনার শিশুর উপযুক্ত চিকিৎসা সম্ভব না হলে শিরার মাধ্যমে স্যালাইন দিয়ে চিকিৎসা করা হবে।

আমাদের এই গবেষণায় অংশ গ্রহণে কোন প্রকার আপত্তি থাকলে অথবা চিকিৎসা চলাকালীন আপনার শিশুকে এই গবেষণা থেকে প্রত্যাহার করতে চাইলেও আপনার শিশুর স্বাভাবিক চিকিৎসার কোন প্রকার ত্রুটি হবে না।

উপরোক্ত বিষয়টি ভালভাবে উপলব্ধি করে আপনি স্বেচ্ছায় এই গবেষণায় আপনার শিশুকে অংশ গ্রহণ করতে রাজী থাকলে নিচে আপনার স্বাক্ষর অথবা বাম হাতের বৃদ্ধাংগুলির ছাপ দিন।

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গবেষকের স্বাক্ষর	অভিভাবকের স্বাক্ষর অথবা বাম হাতের টিপ সহি
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