Attachment 1. Library (2) Date December 15, 19

ETHICAL REVIEW COMMITTEE, ICDDR,B. ICDDR,B LIBRARY DHAKA-12 24.12.87

1) Investigator Dr.S.K.Roy Trainee Investigator (if any)

Application No. 87-026 Supporting Agency (if Non-ICDDR,B) 25

Title of Study Comparison of the clinical and nutritional impact of local and ideal diets used for persistent diarrhoea.

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).

Source of Population:
(a) Ill subjects (Yes) No
(b) Non-ill subjects Yes No
(c) Minors or persons under guardianship Yes No

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)

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

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 NA

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 Committee:
___ Umbrella proposal - Initially submit overview (all other requirements will be submitted with individual studies)
✓ Protocol (Required)
✓ Abstract Summary (Required)
✓ Statement given or read to subjects: 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 complete 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 Ctte for review.

(PTO)

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

S.K.Roy
Principal Investigator

4.12.87
Trainee

DEC 3 1987

87-026

24.12.87

SECTION I - RESEARCH PROTOCOL

1. Title: Comparison of the clinical, and nutritional impact of local and ideal diets used for persistent diarrhoea.

2. Principal Investigator: Dr. S.K. Roy

Co Investigator: Dr. N. Haider

Consultant: Dr. D. Mahalanabis

3. Starting date: As soon as possible

4. Completion date: One year from the starting date

5. Total direct cost: US $:52,261

(Possible source of funding) WHO

6. Scientific Division: This protocol has been approved by the Clinical Sciences Division

Signature of the Head, CSD

10.12.87

Date

7. Abstract summary:

Persistent diarrhoea is a difficult clinical syndrome both to understand its underlying cause and to manage. Severe nutritional deficit and higher mortality are in most part related to the magnitude of derangements of the gastrointestinal functions. One of the most important aspects of the management is dietary manipulation. A local convenient rice-based diet will be compared with an ideal chicken based diet in a randomised controlled clinical trial in 122 infants and children, aged 4 to 24 months, at the metabolic research ward of ICDDR,B and their clinical response studied. Subjects having diarrhoea for more than two weeks will receive the trial diets. Clinical response will be measured and nutritional parameters will be recorded. Subjects will be followed up for 3 months after discharge for appropriate anthropometric measurements and morbidity history. Comparison of duration of diarrhoea, weight gain during and after diarrhoea and their growth rates will be compared. Data generated will be used for identification of appropriate and alternative diet, which may be advised to the persistent diarrhoea patients.

8. Reviews:

a. Ethical Review Committee _____

b. Research Review Committee _____

c. Director, ICDDR,B _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective

To compare the clinical and nutritional impact of a convenient local diet, with those of an ideal diet, in children with persistent diarrhoea.

2. Background

The term 'persistent diarrhoea' is meant to define episodes of diarrhoea that begin acutely, but persist beyond the expected time period for the usual self-limited disease. Many of these prolonged diarrhoea are associated with growth faltering but it is not an inherent part of the definition. Although the time period has not been agreed upon, diarrhoea lasting for longer than 2-3 weeks is usually considered 'persistent' (WHO 1985). Although ranging from irritable bowel syndrome to rare inborn errors of metabolism, all types of prolonged diarrhoea may fall under the term 'chronic diarrhoea', a vast majority would fall under 'persistent diarrhoea' and cause malnutrition leading to a vicious cycle of infection and malnutrition. There have been suggestions (Halliday *et al.* 1982) to call persistent diarrhoea as 'persistent post enteritis diarrhoea syndrome in children'(PPDC). Certain well defined prolonged diarrhoeal illnesses such as Coeliac disease, inflammatory bowel disease, genetically determined illnesses, familial lethal diarrhoeas and blind loop syndrome due to known causes, are considered separately because of established diagnostic and therapeutic entities.

Persistent diarroea has been identified as an important entity since acute diarrhoeal attacks can be overcome with oral or intravenous rehydration solution and antibiotics, as indicated. A estimate for the incidence of persistent diarrhoea is said to be 5-20 percent (Snyder *et al.* 1982) as has been made from the studies which differ among themselves regarding the definition used, selection of patients, age groups and geocultural situation. Studies from U.K. (Avery *et al* 1968), Bangladesh (Black *et al.* 1982), Guatemala (Gordon *et al.* 1971), Australia (Gracey *et al.* 1972), Peru (Perez Flores 1972), India (Ansari *et al.* 1979) and several other countries have shown wide difference in incidence and association of multiple factors with persistent diarrhoea.

The present day information on persistent diarrhoea are not negligible. Studies on etiology have shown different proportion of bacterial and viral agents, many of which are also pathogenic for acute diarrhoea. Their proportion varies widely in different studies. Similarly pathophysiological studies have revealed a wide variety of functional derangement. Those studies have used methodologies such as duodenal intubation and biopsy to examine bile acid metabolism, aerobic and anaerobic overgrowth, brush border enzyme activity, milk protein

intolerance, soyprotein intolerance, hormonal imbalance, pancreatic enzyme deficiency, trace element deficiency, different types of mucosal injury, effect of severe malnutrition, non-specific colitis,and various kinds of changes in the mucosal and submucosal tissue.

Among the above mentioned list of pathophysiologic derangements some are reported more frequently than others. Those include, carbohydrate malabsorption, lactose intolerance, sucrose intolerance, milk protein intolerance, bacterial overgrowth, and steatorrhoea. In order to reach a clear diagnosis of persistent diarrhoea, a number of investigations are to be done, many of which are expensive and need special laboratories with technical expertise in procedures. It is usually impossible to undertake all investigations for routine diagnosis of cases in most developing countries due to limited resources.

In spite of the above mentioned limitations, understanding of pathophysiology and management of persistent diarrhoea have been advanced during last two decades. Studies have documented case fatality rate as high as 70 per cent (Hyman *et al.* 1971) while on later occasion, dietary manipulation has brought down the rate to 40 per cent (Larcher *et al.* 1977). Later studies from India (Ansari et al 1979), UK (Manuel *et al.* 1986), and other countries have reported further reduction of mortality by further improvement in dietary management. Diets free of cows milk, soyabean or complex carbohydrate have been successful. Such diets have been used since 1970's (Harris *et al.* 1977). Among the selective or elimination diets tried, chicken based diet, commonly known as 'comminuted chicken' is widely used. Other diets based on wheat, rice and other cereals have been used to avoid malabsorption. In India Bhave *et al.*, (1985) have shown that rice-dal based diet has achieved success equal to chicken based diet. The inherent properties of the 'ideal' comminuted chicken diet are absence of lactose, sucrose, milk or soyprotein, and complex carbohydrates which are frequently seen to be malabsorbed and cause persistent diarrhoea. There is also less chance of fat malabsorption with this diet because of the absence of long chain fatty acids. In spite of the high efficacy, chicken based diet cannot be prepared easily, it is expensive (1 litre costs US$ 1), difficult to store, and is not feasible for the poorer section of the society. It needs a liquidizer and electricity to make fine particles. This presents a necessity to find an alternative diet, which could be inexpensive, easy to prepare with local ingredients, and has equal efficacy.

In the ICDDR,B diarrhoea treatment centre, a rice-based diet called 'ricesuji' has been used with satisfactory result in the treatment of persistent diarrhoea in young infants aged 4 months and above (Roy SK *et al.* 1987a). Rice based diet is less expensive (1 litre costs 0.26 US$) contains rice powder, egg albumin, glucose and soyabean oil. This diet does not contain lactose, sucrose, milk or soyprotein and much of long chain fatty acids, but it contains starch which is broken down to alpha limit dextrin and maltose. Among the enzymes in brush border, maltase is least affected in persistent diarrhoea or malnutrition. If the salivary and pancreatic amylase are not severely reduced, digestion of starch from rice should be adequate. It has been studied in severely malnourished children with recurrent diarrhoea by Jain et al

(1986) that lipase is more reduced than amylase or trypsin and chymotrypsin in pancreatic secretion. This is relevant to the fact that some of the children suffering from persistent diarrhoea also have malnutrition.

Diets used for persistent diarrhoea are usually less energy and nutrient dense, which are begun at quarter or half strength, and then gradually increased to attain adequate energy and nutrients for maintenance and growth. This is guided by the improvement of gastrointestinal functions. A period of up to three month may be required to attain normal digestive capacity for a persistent diarrhoea patient(Soeparto et al,1983).

Prolonged use of elimination diet has been reported to cause deficiency diseases. It also remains to be known how much recovery of small intestinal mucosal injury is achieved by treating with these diets. The impact of elimination diets on nutrition and subsequent growth can be better evaluated by follow-up studies.

To overcome the malabsorption of sugars due to bacterial overgrowth, treatment of stool pathogen will be considered. Studies have shown that there is significant relationship of stool isolates with that in the duodenal fluid in persistent diarrhoea (Challacombe *et al.*,1974) . Among the aerobic and anaerobic organisms *E.coli* (toxigenic and adherent) *Klebsiella, Enterobacter, B. fragilis,* and *C. difficile* are common (Challacombe *et al.* 1974, Gracey *et al.* 1972).

In a recent study, it has been observed that 88 percent of subjects (4-24 months) have improved with rice-based diet in a median of 5 days (Roy SK 1987b unpublished).

In view of the above information, it is hypothesized that a convenient local diet is as efficient as an expensive ideal diet in respect of clinical, and nutritional benefit in management of persistent diarrhoea.

Rationale

A number of Bangladeshi children are suffering from chronic diarrhoea and use of therapeutic diets will be helpful for their recovery. To date there is no information as to whether non-expensive local diet can be efficient in curing persistent diarroea in place of efficient but expensive diet comminuted chicken. Moreover there is no information on their nutritional impact on the subsequent health, or protection from further diarrhoea.

This study will help to formulate an optimal diet and to make specific recommendation of a convenient diet of therapeutic value for persistent diarrhoea. This may also help to reduce mortality and malnutrition related to persistent diarrhoea.

B. SPECIFIC AIMS

1. To compare the efficacy of a local diet with that of an ideal diet, used in the control of persistent diarrhoea.

2. To compare clinical and nutritional consequences of these diets during persistent diarrhoea.

3. To quantitate the dietary impact on nutrition, morbidity and and subsequent risk during the next three months after discharge.

C. METHODS OF PROCEDURE

Selection criteria

Infants - 4 months - 24 months
diarrhoea with acute origin
duration - more than 2- weeks
sex - male children to facilitate separation of urine from stool
Dehydration status - mild and moderate.

Location around and within Dhaka city for better follow up.

Randomization: Random number will be used for two dietary groups.

Exclusion criterion: Severe infection or fever $\geq 38^{o}c$
Shigellosis, cholera or diagnosed acute diarrhoea patients requiring oral medications (antibiotics),
Kwashiorkor children.

Working definitions:

a) Ideal diet: Comminuted chicken diet will be treated as ideal diet for persistent dirrhoea. This diet has been widely used in many countries with significant success.

b) Recovery of dirrhoea: Passage of soft stool and dirrhoea will be accepted as recovery.

c) Local diet: Half strength rice suji has been termed a local diet.

d) Failure of diet therapy: It is defined as continuation or increase in diarrhoea after at least seven days with the study diet.

PROCEDURES:

A. 1. Consent

2. Clinical history

3. Clinical examinations

B. INVESTIGATIONS:

1. Blood electrolytes, CBC, RBP, (will be measured to compare protein synthesis during recovery).

2. Stool M/E

3. Stool pH and reducing substance

4. Stool c/s for *Campylobacter, ETEC, EPEC, Cholera, Shigella, Salmonella* and ELISA for *Rotavirus*

5. Permeability test (measurement of lactulose and mannitol) will be performed at Day 1, Day 7 and at recovery.

6. X-ray if indicated

7. Urine examination and c/s if required

C. <u>General management</u>

A baseline data on output of stool, vomitus, breast milk, milk feed and i.v. fluid will be obtained for 24 hours before putting into study diet.

Eligible patients will be randomly allocated to either diet group, A) with local rice based diet, or B) ideal chicken based diet.

Initial rehydration in 1st 24 hrs will be done by intravenous fluid electrolyte solution irrespective of the dietary group (as malabsorption and high osmolality may be contributed by WHO-ORS or Rice-based ORS). I.V acetate will be given @ 20 ml/kg for mild and @ 50 ml/kg/4hr. for moderate dehydration. Initial feed will be given with diets started in acute diarrhoea (half-strength milk suji). Breast feeding will be continued and measurement will be done.

Diet will be given to aim 100 kcal/kg/d keeping oral fluid volume below 200 ml/kg/d. Hourly feed will be given.

Permeability test:

A non invasive permeability test will be performed which will give information on mucosal damage related to persistent diarrhoea and growth rate. Improvement of the mucosal damage will be compared in two dietary groups. Permeability test will be done before the study diets are begun. Infants will be given a freshly prepared drink containing 5 g lactulose with 0.5 g lactose (7.5 ml Duphalac) and 1 g mannitol in 20 ml 1% chloroform water. Breast feeding and fluid intake will be encouraged during the period. Urine samples will be collected for 5 hours into uribags. One drop of 20% V/V chlorohexidine gluconate will be added to each bag before collection. Urine volume will be measured and recorded. Aliquots (5 ml) will be taken and stored at -20°C. Lactulose will be measured using an automated enzyme assay system (Behron R, 1983). Mannitol can be assayed by using a similar assay based on oxidation of the sugar by mannitol dehydrogenase prepared from Leukonostomesenteriodes (Yamanaka K, 1975).

Dietary Schedules

To minimize the cost of the study only two diets will be compared. Local diet for Bangladeshi infants and children will be rice based, the composition being given below. In breastfed subjects lower volume may be required. Diet will be continued for 7 days and more while improvement is achieved. In case of failure after 7 days with one diet, the other diet will be given in a cross over trial. A total of two weeks will be the expected duration of study diet before milk feed is given. The protein energy ratio of rice based diet will be 8% which will ensure adequate growth in presence of adequate energy. Commminuted chicken diet will have 26% protein which is due to its main component, chicken. Any benefit due to excess protein will be examined in this comparative study.

Local diet

Milk, soya, sucrose free -	Rice based diet (Half-strength)
Rice powder	30 g = 1 oz = 1/2 chatak
Egg white (albumin)	15 g
Oil coconut	15 g (3 teaspoonful)
Oil soybean	5 g (1 teaspoonful)
Glucose	25 g (1/2 chatak)
Magnesium chloride	1 g
Calcium lactate	1 g
Kcal	1 g
Nacl	1 g
Water up to	1000 ml
Energy	40 kcal/100 ml
Protein	0.94 g/100 ml
PER	9%
Fat energy ratio	45%
Osmolality	218 mosm/kg

Multi vitamins containing vit A, B-complex and C will be given daily. Zinc syrup (50 mg zinc acetate) will be given to all patients for two weeks to provide essential nutrients to prolonged sick patients. Elemental diets have been shown to cause micronutrient deficiency. It is also standard practice in other gastroenterology units to provide a metabolite mixture as a part of therapy(Harries .J.T.1980).

Ideal diet - (Composition / Litre)

Milk, soya, sucrose, maltose, starch free : 'comminuted chicken' (Half-strength)

Minced chicken	90 g
Oil coconut	15 g
Oil soybean	5 g
Glucose	20 g
Onion	10 g
Kcal	1 g
Nacl	1 g
Magnesium chloride	1 g
Calcium lactate	1 g
Water up to	1000 ml
Energy	34 kcal/100 ml
Protein	2.2 g/100 ml
PER	26%
Fat energy ratio	40%
Osmolality	200 mosm/kg

Morbidity and anthropometry data collection.

After recovery from diarrhoea patients will be sent home with transition to home diet. To see the nutritional impact a weekly follow-up visit will be made for measurements of anthropometric parameters (body weight, length /height, mid arm circumference) for 3 months after discharge. Morbidity history will be collected every week for 3 months to compare the confounding variables. Recall method will be used for morbidity data and feeding history. Trial with cow's milk will be given after 2 weeks after recovery at the hospital follow up for 6 hours and symptoms will be recorded by the investigators in a designed flow sheet.

In case of non-response to improvement of diarrhoea, rice diet will be replaced with 'comminuted chicken' after 7 days and vice versa. If patients do not improve with both diets they will be treated as needed. Any patient developing complications justified for intensive care with NPO will be excluded from study and will be transferred to I:C.U.

D. Statistical Calculation

As there is no published data on nutritional impact or on the difference in duration for recovery with these diets we shall use our own data for calculation of the sample size.

Assuming hypothesis that clinical success will be equal by both diet, the difference in rate of success will be zero. Null hypothesis will be that difference in between the success rates with chicken and rice-suji diet is insignificant. Hypothesis will be rejected if the difference is significant.

Calculation for sample size - (Ref. Roy SK 1987b)

P_1cc = 90% (P_1 cc = proportion of success with comminuted chicken diet)

P_2 RS = 70% (P_2 RS = proportion success with rice based diet)

With expected difference of 20%, and type 1 error 5% and type 2 error 20%, N will be 61 in each group. Sample size is calculated according to Cockran et al (1980).

$$n = \frac{p_1 (100 - p_1) + p_2 (100 - p_2)}{(p_1 \pm p_2)^2} \times f(\alpha, \beta)$$

Total n = 61 x 2 = 122 (130 for 8 rejections)

Variables:

1. Duration of diet therapy for improvement
2. Proportion of success in each diet
3. Energy and nutrient intake
4. Stool volume, frequency
5. Mucosal permeability
6. Stool pathogens, pH and reducing substance
7. Growth rate after discharge : g/kg/month, cm/100 cm/month, MUAC
8. Weight gain during and after therapy
9. Frequency and duration of morbidity during the follow up period
10. Response to cow's milk

Analyses of Data

Data generated from the study will be entered into microcomputer and appropriate test will be done. Analysis of variance, cross tabulations, Chi-squared test, proportion test, non-paired student's *t* test, Wilcoxon's Rank/sign test and multiple regression analysis for relationships will be considered.

D. SIGNIFICANCE

This study will generate information on efficacy of local diet during persistent diarrhoea. The comparison with an ideal diet will be reasonable to justify its application to appropriate population. The impact on clinical and nutritional benefit will address also the issue of elimination diet for recovery of persistent diarrhoea. The above knowledge will be of special help to formulate a local convenient diet for clinical and nutritional benefit to reduce persistent diarrhoea related morbidity and malnutrition.

E. FACILITIES REQUIRED

1. Office space: present space will be used
2. Laboratory space: clinical research unit, liquidizer.
3. Hospital bed metabolic ward will be used
4. Rent, communication, utilities: ICDDR,B transport may be used.

ABSTRACT SUMMARY FOR ETRICAL REVIEW COMMITTEE

1. The project aims at caring for the most vulnerable infants and children suffering from persistent diarrhoea through application of efficient diets and will investigate on quantitative parameters of digestive derangements. Children less than 2 years are most vulnerable and will receive standard care at hospital with a back up care for next 3 months.

2. None of the investigations are harmful to any child.

3. Informed consent will be obtained from parents or guardian of each infant. Code number will be applied to ensure confidentiality.

4. There will be immediate benefit to the study child by investigation results, special care, monitoring and appropriate dietary and treatment measures. Back up service during follow up period will substantially benefit them.

5. The blood volume required will be minimal (4 ml) for routine investigations. Stool and urine will be collected for necessary investigations and nutrient estimation.

6. Patients records and generated data will be necessary for data analysis, evaluation and preparation of manuscript.

7. Transport fare will be paid to the parents for follow-up.

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SECTION II - BUDGET (DETAILED)

1. Personal services: (cost estimated on 1988 budget.)

Name	Level	Position	%Effort	Time	Annual salary (US$)	Total
Dr. S.K. Roy	NOC	Pr. Investigator	50%	1 year	4,800	
Dr. R. Haider	NOA	Co-investigator	25%	1 year	2,268	
Medical Officer	NOA	Co. Investigator	25%	1 year	1,872	
Dietician	L.VI		25%	1 year	1,554	
Research Off	L.VI		25%	1 year	1,554	
Urban Volunt(3)	L.III		100%	1 year	1,800	
Nutrition workers (2)	L.V		100%	1 year	8,500	
						22,348

2. Supplies & material:	Drugs	500	
	Hospital supplies	500	
	Stationeries	500	
			1,500

3. Rent, communication utilities			
Transportation of patients & staff		2,500	
Printing & publications		500	
			3,000

4. Interdepartmental services			
Laboratory tests:	Pathology - Blood CBC	463	
	Stool M/E	400	
	Urine M/E	450	
Microbiology:	Stool C/S	500	
	ELISA	600	
	E. coli	500	
	Cholera	400	
	Shigella	400	
	Salmonella	600	
	EPEC	500	
Biochemistry -	Albumin	700	
	Electrolytes	1000	
	EBP	3200	
	X-ray	200	
	Permeability test	1000	
	Pnt.hospitalization	14,000	

(BUDGET SUMMARY)

	US Dollars
Personnel services	22,348
Supplies	1,500
Other	3,000
Interdepartmental	25,413
Total direct cost:	52,261
Incremental overhead 30%	15,679
Grand total:	67,739

International Centre for Diarrhoeal Disease Research, Bangladesh

CONSENT FORM

Patient No. __/__/__/__/__/__/__/__/

Date: __/__/__/__/__/__/

IMPACT OF DEFINED DIETS ON PERSISTENT DIARRHOEA

[This will be read out and explained clearly before the consent is obtained]

Your child is suffering from diarrhoea which is prolonged till now and it takes usually a longer period for recovery. There is a great deal of deficiency in knowledge about this problem along with therapeutic outline for its management.

We are taking all care to improve the management of this persistent diarrhoea problem and for a better understanding, a research project is looking at this patients. This research work may lead to a better answer of the problem to help your child getting earlier recovery and the results will be helpful in future management for all similar cases. There is no risk in this study.

If you agree to put your child in this study the following steps will be applicable to him/her.

1. He/she will be kept in the metabolic ward to collect stool, urine, and vomitus accurately.

2. For routine examination stool, urine, and 4 ml of blood will be obtained in the beginning of the study.

3. Small amount of sugar solution (30 ml) will be fed to examine the condition of his/her intestine related to the disease.

4. He/she will receive intravenous saline and appropriate treatment required.

5. He/she will be followed up weekly for 3 months after the diarrhoea is cured. You will receive transport fare if required.

You will always be at liberty to withdraw your child from the study, yet he/she will receive the standard care.

Signature of the Pr. Investigator

Signature/Thumb impression of the Guardian

Date: _____

Form

Daily clinical Data

(Comparison of diets study)

Stool freq	Consistency	Fever	Heart rate	Lungs	dist abd sound

Form 2

Daily clinical sheet, fluid chart

(Comparison of diet study)

IV fluid	Stool volume	Urine volume	Water

Form 3

Daily clinical sheet -- Food intake

(Comparison diet study)

8-9 a.m.	Breast milk	Test diet vol. given	Diet left	Intake	Vomit

আই সি. ডি. ডি আর বি

সম্মতি পত্র

রোগী নং: __|__|__|__|__|__

তারিখ __|__|__|__|__|__

দীর্ঘস্থায়ী ডায়রিয়াতে কার্যকর খাদ্যের তুলনামূলক গবেষণা

(সম্মতি গ্রহণের পূর্বে অভিভাবককে পূর্ণ ব্যাখ্যা করিয়া পাঠ করিয়া শুনানো হইবে)

আপনার শিশু দীর্ঘস্থায়ী ডায়রিয়াতে ভুগিতেছে যাহা সারিতে সাধারণত: যথেষ্ট দীর্ঘ সময় প্রয়োজন হয়। এখনও পর্যন্ত এই রোগের চিকিৎসার জন্য প্রয়োজনীয় জ্ঞান অর্জিত হয় নাই।

আমরা এই রোগের চিকিৎসার জন্য অত্যন্ত চমৎকার যত্ন নিতেছি এবং প্রয়োজনীয় জ্ঞান লাভের জন্য একটি গবেষণা প্রকল্প নিয়াছি। এই গবেষণার ফলে হয়ত লব্ধ জ্ঞান দ্বারা আপনার শিশুর চিকিৎসা আরো সুন্দর হইবে এবং ভবিষ্যতে এই কঠিন পীড়া আক্রান্ত শিশুদের উন্নত চিকিৎসার পথ সুগম হইবে। এই গবেষণায় কোন প্রকার ক্ষতির ঝুঁকি নাই।

আপনি রাজী হইলে নিম্নোক্ত পদক্ষেপগুলি আপনার শিশুর ক্ষেত্রে প্রযোজ্য হইবে।

১। আপনার শিশুকে আলাদা কক্ষে রাখিয়া চিকিৎসা সহ মল, মূত্র, বমি সংগ্রহ করা হইবে।

২। সাধারণ চিকিৎসার জন্য প্রয়োজনীয় রক্ত (৪ সি.সি), মল ও মূত্র নেওয়া হইবে।

৩। অল্প পরিমাণ চিনির শরবৎ খাইতে দিয়া মূত্র সংগ্রহ করা হইবে।

৪। আন্ত্রিক সেলাইন ও যথাযথ চিকিৎসা দেয়া হইবে।

৫। ভাল হইবার পরবর্তী ৬ মাস - তাহার শরীর সুস্থ ও সুন্দর ভাবে বৃদ্ধিলাভ করিতেছে কিনা তাহা জানার জন্য সপ্তাহে একবার দেখা হইবে। আসিলে আপনাকে যাতায়াত ভাড়া দেওয়া যাইতে পারে।

যে কোন সময় ইচ্ছা করিলে আপনি শিশুকে গবেষণা হইতে ছাড়াইয়া লইতে পারেন তথাপি তাহার যথারীতি চিকিৎসা চলিবে।

প্রধান গবেষকের স্বাক্ষর

অভিভাবকের স্বাক্ষর / টিপসই