Attachment 1.

Date 24.4.1981

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator DR. P.K.BARDHAN & DR.A.M.MOLLA

Application No. 81-019

Trainee Investigator (if any)

Supporting Agency (if Non-ICDDR,B) Nil

Title of Study GASTRIC EMPTYING TIME IN CHILDREN WITH ACUTE DIARRHOEA DUE TO DIFFERENT ETIOLOGIES

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.

Principal Investigator

Trainee

81-019
recd 28/4/81

SECTION I - RESEARCH PROTOCOL

1. Title : GASTRIC EMPTYING TIME IN CHILDREN WITH ACUTE DIARRHOEA DUE TO DIFFERENT ETIOLOGIES

2. Principal Investigators : DR. P. K. BARDHAN
   DR. A. M. MOLLA

3. Starting Date : June, 1981

4. Completion Date : December, 1981

5. Total Direct Cost : US $ 22,551.

6. Scientific Programme Head: This protocol have been approved by the Pathogenesis and Therapy Working Group.

Molla for Programme head.
Signature of Scientific Programme Head

Date 27.4.81

7. Abstract Summary :

The common types of acute infective diarrhoeas in children are often associated with nausea and vomiting without any obvious histopathologic change in the gastric mucosa, suggesting possible involvement of gastric functions. Determination of gastric emptying time is a reliable and useful method for assessment of gastric motor activities. 50 children below the age of 5 years suffering from acute diarrhoea (duration 24 hrs.) due to different etiologies with moderate to severe dehydration and no antibiotic treatment outside will be studied. All hydration will be with I.V. fluids. Antibiotics will be given when clinically indicated, and no restriction on food will be made except the few hours necessary for the performance of tests. The gastric emptying test will be followed by D-Xylose absorption test, and both these tests will be performed during acute illness as well as in convalescent stage. The gastric emptying patterns in acute and convalescent stages will be compared and correlated with the results of D-Xylose absorption tests. These data will be helpful for better understanding of the pathophysiological mechanisms of diarrhoeal diseases.

8. (a) Research involving human subjects: _____

   (b) Research Review Committee: _____

   (c) BMRC : _____

   (d) Director : _____

   (e) Controller/Adminstrator : _____

SECTION II - RESEARCH PLAN

Gastric Emptying Time in Diarrhoea in Children Due to Different Aetiology

A. Introduction

1. Objective: To examine the possibility of abnormal gastric motor function by assessment of gastric emptying pattern in acute diarrhoeas of different aetiologies.

2. Background: The commonest types of acute diarrhoeas are associated with nausea, vomiting, and other constitutional symptoms of varying degrees. The occurrence of nausea and vomiting, despite the absence of obvious histopathological changes in the gastro-intestinal mucosa in most of these cases suggests the possibility of abnormal gastric function. A reliable method for assessment of the effects of gastric motor function can be obtained by the use of gastric emptying tests[1].

The present understanding of the normal control and regulation of gastric emptying has been established by investigations spanning more than 100 years [2]. Food, on entering the stomach, is initially accomodated in the proximal stomach without any rapid rise in the intra-gastric pressure due to the ability of the fundus to relax, the process being known as 'receptive relaxation'[3]. The response to food by the distal stomach is much vigorous, the characteristic feature being peristaltic waves sweeping towards the pylorus to terminate in the distal antrum. The more active waves result in strong segmental contraction of the gastric antrum (antral systole), which in turn is co-ordinated with duodenal muscular activity. However, food does not always pass into duodenum, and frequently the antral contents are

retropulsed[4]. The rate of emptying from the stomach (of liquids) is also dependent on the pressure gradient between antrum and duodenum[5].

The regulation of gastric emptying and motility involves a variety of chemical and neural mechanisms. While these are evoked by the presence of food, their initiation is multifactorial. Their modes of action involve stimulation at the various types of receptor sites. It is now known that the rate of gastric emptying is influenced by volume[6], consistency, and the nature of the foods eaten[7]. Duodenal receptors that are sensitive to pH, osmolality, fats, and possibly amino-acid content help regulate gastric emptying by mechansims not yet fully explained, although neural mechansims (entero-gastric reflex) are probably important [7]. It has been suggested that the energy-density of food provides a unifying control mechansims governing the emptying rate[1]. Recently, a strong possibility of relationship between food intake and gastric emptying has been suggested[8]. Hormones also affect gastric emptying. Gastrin, secretin, cholcystokinin - pancreozymin, pancreatic glucagon, vasoactive intestinal polypeptide and "enterogastrone" all are capable of delaying gastric emptying, whereas motilin increases motor activities of fundic pouches. However, their physiologic roles are still unclear[7]. Lastly, gastric emptying is influenced by both intrinsic and extrinsic nerve supplies of the stomach, as well as numerous reflex paths mediated from higher centres in the spinal cord, mid-brain and medulla[1].

Changes in gastric emptying has been documented in a number of grstro-intestinal and other diseases [9]. Experimental injury to the small intestinal mucosa of rats induced by various chemical agents has uniformly resulted in slowing the rate of gastric emptying and the degree of delay is well correlated with the severity of nucosal injury [10]. Staphylococcal enterotoxin B, which causes mild, short lived villous injuries in rhesus monkeys[11], is shown to be capable of inducing gastric retention [12]. It is now established that rotavirus infections are characterised by invastion and desquamation. of mature villous cells, leading to small intestinal mucosal lesions[13], though gastric fundic and antral mucosa remain morphologically unchanged[14]. However, any abnormality in gastric emptying in rotavirus infections is not improbable, as most of the known mechanisms of control of gastric emptying involve feedbock mechanism from proximal small intestine. In fact, it has been shown in human volunteers that gastroenteritis caused by ingestion of parvo-virus like agents - Norwalk and Hawai viruses, is associated with marked delay in gastric emptying during acute illness [15].

In cholera, the diarrhoea is caused by an enterotoxin which induces active water and electrolyte secretion mediated by cyclic AMP. This disease is not associated with any significant histopathological change, and the small intestinal mucosa is normal, except for goblet cell mucos depletion[16], though presence of mucosal injury has been claimed [17]. High serum levels of certain gastrointestinal hormones, viz. gastrin, secretion, VIP and glucagon in clinical cholera patients has been reported [18], all of which are capable

of modifying gastric motility. Whether clinical cholera is associated with altered gastric emptying is yet to be investigated.

On the other hand, shigellosis is characterised by an acute inflammatory response, mostly in the colon, resulting in destruction of villous tips, distortion of the mucosal architecture and formation of micro-abscesses. Shigella dysenteriae I and certain strains of S. flexneri and S. sonnei produce on enterotoxin capable of stimulating intestinal secretion, though its exact role is not yet clear [19]. Histological abnormalities have been observed in small intestinal mucosa exposed to shigella enterotoxins [16]. Whether these mucosal lesions, both inflammatory and non-inflammatory, seen in shigellosis, have any possible association with gastric emptying is yet to be studied.

It seems likely that the rate of gastric emptying into the small bowel influences small intestinal transit[9]. Rapid intestinal transit time and reduced small intestinal absorption are observed in most types of acute infectious diarrhoeas[20]. Though the exact mechanism of production of these abnormal functions are not clear, there exists the possibility of involvement of gastric motor functions.

In view of the above background, this study proposes both qualitative and quantitative assessment of gastric emptying is diarrhoeas of different aetiologies in children below 5 years.

3. Rationale: Any disturbance in gastric emptying is likely to have direct influence upon oral intake of any form, including oral rehydration fluids, foods, and drugs, as well as their delivery into the duodenum, thus affecting both nutritional and clinical management of patients suffering from diarrhoeas. It is also improtant to examine any possible correlation between any abnormal gastric emptying and the reduced intestional absorptive capacity observed in acute diarrhoeal episodes in children.

Since the available information regarding this problem in insufficient, it will be worthwhile to investigate. The informations from such a study will be of great value in interpreting the results of many absorption tests e.g. xylose absorption test.

B. Specific Aims:

(1) To determine the gastric emptying time in acute infectious diarrhoeas due to different aetiologies during illness and after recovery.

(2) To examine the possibility of correct interpretation of D-xylose absorption test in diarrhoea.

C. Methods and Procedures :

Gastric emptying time will be measured in diarrhoea due to cholera, rotavirus, ETEC and shigella. 5-10 patients below 5 years of age from each group of aetiology will be selected for the study. In order to accomplish this, 50 children with moderate to severe degree of dehydration and relatively shorter duration (24 hrs) and no antibiotic treatment outside will be admitted. Informed consent from the parents will be obtained before inclusion of the patients in this study. Children with complications like Br. pneumonia, high fever, electrolyte imbalance, hypoglycaemia and PCM will be excluded.

All children will be given a thorough physical examination, anthropometric measurements (Ht, Wt, mid upper arm, head and chest circumferences) will be taken and a detailed clinical history will be obtained.

The initial rehydration and subsequent maintanance of hydration will be done by I.V. fluids only. Antibiotics will be given, when clinically indicated. There will be no restriction on water or food, except for the few hours necessary to perform the gastric emptying and D-xylose absorption tests. During fasting periods, the patients will be under parenteral glucose cover.

On admission the following lab. investigations will be done.

Finger blood - TC, DC, HCT and Sp. Gravity.

Blood - Electrolytes, urea and creatinine

Urine - analysis.

Stool - Microscopic analysis.

Rectal swabs will be taken and plated on Mac-conkey's agar, SS Agar, Mansur's and TCBS media. Agents looked for will include V. Cholera, ETEC, Salmonella, shigella and rotavirus.

These tests, as well as any other test, may be repeated on clinical grounds.

Patients will be discharged after clinical recovery. Apropriate course of medicines will be given to the patients having ova or cysts in thier stool at the time of discharge.

Exclusion from the study:

Development of any complication will cause exclusion from the study. The excluded patients will be transferred to the general ward for proper treatment.

Gastric Emptying Test: For studying the rate of gastric emptying the dye dilution and double - sampling technique of George [21] will be used. Essentially, this technique consists in determining the concentration of a marker dye before and after intragastric adjunction of a known amount of the marker dye. However, this method does not take into account the contribution of the volume of endogenous gastric secretion, which can be estimated by concurrent Cl^- determination[22].

The stock solution to be used as a marker will contain 1 gm/litre of phenol red in distilled water. The concentration of phenol red in the test meal will be 50 mg/litre of distilled water. The PH of both the stock solution and the test meal will be adjusted to 7.0 with sulphuric acid. The amount of test meal to be given will be calculated for every individual patient (450 ml/m^2 of body surface area). Body suface area will be calculated from Ht. and Wt. of the patient by using a normogram[23].

Before the use of the stock solution and the test meal, their exact concentration will be determined on the day of test by taking aliquots, since a slight daily change in dye concentration has been noted. Determination of the concentration of phenol red in these solutions as well as all the samples from gastric aspiration will be determined in a spectro-photometer at 560 nm.

Technique of Test:

1. A nasogastric tube will be passed into the stomach of the patients, who will be kept fasting from midnight. This procedure will be preceded by parential administration of a mild tranquilliser (diazepam) in therapeutic dose. The tube will be positioned under fluoroscopic control in the most dependent part of the stomoach, and then secured firmly to the uppper lip with adhesive tape. The patients will be kept supine and tilled 30-45^{o} head up throughout the test.

2. The resting juice will be removed, and the stomach washed out with 100-200 ml of distilled water.

3. The calculated amount of test meal will be instilled into the stomach within 2 minutes, and the time noted.

4. At exactly 10 minutes, 5 ml of gastric contents will be withdrawn. The plunger of the syringe will be then removed and 10 ml of stock soln will be added by pipette and then instilled into the stomach. Mixing in the stomach will be achieved by withdrawing and re-inserting syringefuls of gastric contents for about 1 minute, and following this, another 5 ml of gastric contents will be obtained.

5. This procedure will be repeated every 10 minutes until the stomach is almost empty.

6. Some difficulty in withdrawing fluids may then be encountered, and it may be necessary to move the gastric tubes to find the remaining fluid and withdraw as much fluid as possible. The stomach will then be washed out by 100-200 ml of distilled water.

Calculation:

If V_1 = Volume of gastric contents to be determined

V_{A1} = Volume of sample withdrawn from V_1

V_2 = Volume of concentrated stock soln added to V_1.

C_1 = concentration of phenol red in V_{A1}

C_2 = concentration of phenol red in V_2

C_3 = Final concentration of phenol red after addition of V_2

then the value of V_1 may be obtained by the following formula,

$$V_1 = V_2 (C_2 - C_3) / (C_3 - C) + V_{A1}$$

Now, if R = concentration of Cl^- in V_1 (in mM/LO and V_o = Amount of original test meal present in V_1 (in litres)

then $V_o = V_1$ (in litres) - $\frac{V1 \times R}{140}$

assuming the mean concentration of Cl^- in the secretions entering the stomach is 140 mM/L

These calculations witll be repeated for every batch of samples taken at 10 minute intervals, and volumes of the original test meal remaining in the stomach at 10 minutes intervals will be determined.

Total Intestinal Transit Time: The time of giving the test meal will be noted, and the time of first appearance of phenol red (as seen by red coloured stools) will also be noted. The difference will give the total intestinal transit time.

D-xylose absorption test: This test will be performed the next day after gastric emptying test. After fasting from midnight, 5gms of xylose will be given by mough at 6:30 a.m. and 1.5 ml of venous blood will be collected at 7:30 a.m. after which food will be given to the patient.

Follow-up study: The same patients will be brought back to the hospital after 2 weeks and kept for 48 hours. The gastric emptying test and D-Xylose absorption test will be repeated. A rectal swab will be taken, and the same agents will be looked for.

Data Analysis: Regression equations for both the log values and the square roots ofthe estimated volumes against time will be calculated in each of the tests using the least square method. The regression method

showing better degree of fitness, as judged by higher correlation co-efficient in greater number of tests will be selected for further calculations. The defining parameters of gastric emptying will be obtained from the selected regression equation from each test. The three defining parameters are:

a. Total emptying time - defined as the time taken for the volume of the gastric contents to become reduced to 10 ml.

b. Half-time of emptying ($T_{\frac{1}{2}}$) - defined as the time required for the volume of the stomach to fall by half.

c. Starting Index - defined as the number of minutes before or after zero - time at which the extrapalated regression line reaches the value of the original voume of test meal instilled into the stomach. A negative index indicates rapid emptying at the initial stage, whereas a positive index occurs when initial emptying is slow.

In each aetiology, the differences (if any) between the values of each parameter in the acute and convalescent stages will be tested by the paired "t" test. (e.g., $T_{\frac{1}{2}}$ between acute and convalescent stages in rotaviral diarrhoea). Statistical significance will be accepted at the 5% level of probability.

D. Significance: Reduced food intake is observed during acute diarrhoeal episodes in children [23], vomiting is also an often encountered problem in acute diarrhoeal diseases, particularly in paediatric age groups. Both of these problems are suggested to be influenced by gastric emptying. There has been no specific study performed about gastric emptying pattern

in acute diarrhoeal in children due to different aetiologies. The proposed study will provide important information which will help to understand the pathophysiological mechanisms of diarrhoeal diseases, particularly the effect of different diarrhoeal agents on the motor function of stomach and duodenum.

E. Facilities Required:

1. Office Space - the present study room will be used. No extra space is necessary.
2. Laboratory space - Existing ICDDR,B lab. facilities will be utilised.
3. Hospital resources - Existing facilities in the study ward will be utilised.
4. Animal resources - 200 suckling mice will be necessary for E. coli ST assay.
5. Logistic support - Data processing & computer support from the Data Management Branch of ICDDR,B will be necessary.
6. Transport - It will be supoorted by the existing transport facilites.
7. Major items of equipment - Nil
8. Others - None.

F. Collaborative Arrangements - Nil.

REFERENCES

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SECTION III - BUDGET

Detailed Budget :

1 . Personnel Service :

Name	Position	% Effort	Project requirment Tk.	$
Dr. P. K. Bardhan	Principal Investigator	30 %	10,000	-
Dr. A. M. Molla	Scientist	5 %	-	1,000
Physician (to be named)		20 %	6,000	-
Staff Nurse - 3		40 %	20,000	-
Sr. Research Technician, Biochemistry.		30 %	7,000	-
Technician, Microbiology		1 person month	2,000	-
Technician, Clin. Path.		1 person month	2,000	-
Veterinarian			1,000	-
Field Asstt.			4,000	-
Statistician			11,000	-
			53,000	1,000

2. Supplies and Materials :

Office Supplies :		1,000	-
Chemicals :		4,000	400
Lab. Tests			
FB for TC DC HCT	50 tests	210	-
Blood Electrolytes & Creatinine	50 tests	180	-
Urine M/E	50 tests	125	-
S tool M/E	100 tests	205	-
Stool Culture	100 tests	2,500	-
Y1 Adrenal Cell Assay	500 isolates	1,000	-
Infant Mouse Assay	200 isolates	2,000	-
ELISA Test	100 specimens	300	-
		11,520	400

3. Equipments	-	100
4. Patient Hospitalisation - 600 patient days	90,000	-
5. Outpatients	-	-

6. Transport - 1,000 patient miles	3,000	-
7. Travel -		3,000
8. Rent -	-	-
9.Transport of Things	-	-
10. Printing and Publication -	3,000	300
11. Contractual Services - Computer time - 4 hrs.	4,000	-

SUMMARY BUDGET

	Tk.	$
1. Personnel Services	53,000	1,000
2. Supplies and Materials	11,520	400
3. Equipments	-	100
4. Patient Hospitalisation	90,000	-
5. Outpatient	-	-
6. Transport	3,000	-
7. Travel	-	3,000
8. Transportation of things	-	-
9. Rent	-	-
10. Printing and Publication	3,000	300
11. Contractual Services	4,000	-
	164,520	4,800
	Total US	$ 15,702
+130%	Overhead	$ 4,731
	Total	$ 20,501
+ 10%	Inflation	$ 2,050
	Grand Total	$ 22,551

ABSTRACT SUMMARY

1. Many diarrhoeal patients, mostly children, are clinically observed to have gastric retention, and are treated with naso-gastric suction. Vomiting, one of the main reasons for failure of oral therapy is also mostly noted among the children. Moreover, rotavirus infection, which has the highest possibility of being associated with disturbances of gastric emptying (as documented in the adult volunteer study) is mostly confined to the age group 6 months - 2 years, where it is the commonest diarrhoeal pathogen. As such, they are likely to be the most benefited group from the outcome of this study.

2. The method of naso-gastric intubation is a very common hospital procedure, and is regularly performed in the clinical wards of this centre. The only potential risks are that of haemorrhage and perforation. The occurence of these complications are calculated to be less than 1 in 100,000[25]. We have never observed these complications in this centre. This procedure is however, associated with some discomfort to the patient. There are no other social or legal risks. The only other reliable method available for studing gastric emptying is by using radioactive isotopes, which is risky to use in children, particulary in the 6 months - 2 years age group, and moreover needs highly sophisticated and expensive equipments which are not available in this centre nor are being planned to be purchased.

3. For protection against potential risks, a blunt-ended double-lumen soft rubber tube will be used, and will be guided under fluoroscopic guidance. The double-lumen tube will prevent any suction or subsequent injury to the gastric mucosa. The patient will be under sedation to reduce discomfort.

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. Interview will be taken in the hospital to obtain clinical history.

7. If any significant disturbance of gastric emptying is observed in any individual patient, then appropriate standard therapeutic measures will be taken for that patient. The results of this study may help to modify the future approach towards the clinical management of diarrhoeal patients, particularly children, mainly to increase food intake, and to reduce the severity and frequency of vomiting.

8. The use of hospital records and body-fluids will be required.

CONSENT FORM

(STATEMENT READ AND CLEARLY EXPLAINED TO THE SUBJECT WHEN CONSENT IS OBTAINED)

ICDDR,B is carrying out research to find out any disturbance of the emptying of foods from the stomach during diarrhoea. This will help us to provide better treatment to the patients, as well as to understand better the disease process. We like you to join in the study for the well-being of mankind.

If you decide to participate in the study, you can expect the following :

1. Your child will be given all necessary care.
2. It will be necessary for you to stay at least 3 days or even more until diarrhoea stops.
3. After midnight, the patient will not be given any food before the completion of the tests in the next morning.
4. A thin rubber tube will be passed through nose into the stomach of the patient under fluoroscopic guidance. To reduce discomfort, we will give a sedative to the patient. This is a safe procedure, and are being done regularly in this centre.
5. After that, we will put some distilled water mixed with a harmless chemical called phenol red into the stomach through the tube, and from time to time will withdraw the fluid or add some more of the fluid. This will not cause any harm.
6. 2½ hours after introduction of the tube, it will be taken out and food will be given to the patient.
7. The next day we will give 5 gm. of D-Xylose to the patient in the morning, and after 1 hour 1 cc of blood will be drawn.
8. You will be advised to return with your child 2-3 weeks after you are discharged, when these tests will be repeated.

We will take care of your child even if you do not join in this study, or withdraw from the study at any time.

If you are willing voluntarily to join in this study, then please sign your name or give left thumb impression.

Signature of Investigator

Date :_____

Signature or left thumb impression of parent

Date :_____

সম্মতি পত্র

(সম্মতি গ্রহণের পূর্বে রোগীর অভিভাবককে নিম্নোক্ত বিষয় ভাবে বুঝিয়ে দেয়া হল)

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র টাইফয়েড রোগে পাকস্থলী হতে খাবার নিঃসরণে কোন অসুবিধা হয় কি না তা জানার জন্য গবেষণা চালাচ্ছে। এই গবেষণা আমাদেরকে এই রোগের চিকিৎসা ব্যবস্থা উন্নত করতে এবং এই রোগ সম্বন্ধে আরো জানতে সাহায্য করবে। আমরা আশা করি মানব জাতীর কল্যাণে আপনি এই গবেষণায় অংশগ্রহণ করবেন।

আমাদের এই গবেষণায় অংশগ্রহণে ইচ্ছুক ও সহায়ক হলে নিম্নোক্ত ব্যবস্থাদি গ্রহণ করা হবে-

১। আপনার শিশুর উদরাময় রোগের সুচিকিৎসা করা হবে।

২। রোগী সুস্থ্য না হওয়া পর্যন্ত অন্ততঃ ৩ দিন কিংবা প্রয়োজনে তার বেশী সময় হাসপাতালে থাকতে হবে।

৩। রোগীকে মাঝরাতের পর পরদিন সকালে পরীক্ষা সম্পূর্ণ না হওয়ার আগে পর্যন্ত খাবার দেয়া হবে না।

৪। একটি পাতলা রাবারের নল রোগীর নাক দিয়ে তার পাকস্থলীতে পরিচালনা করা হবে। এই নলের মাধ্যমে আমরা এন্ডোস্কোপের সাহায্যে দেখব। এটা একটা নিরাপদ পরীক্ষা। এবং এই হাসপাতালে নিয়মিত ভাবে করা হয়।

৫। এর পর ফিনোল রেড নামক একটি কেমিকেল মিশ্রিত বিশুদ্ধ পানি এই নল দ্বারা রোগীর পাকস্থলীতে পাঠানো হবে এবং কিছুক্ষণ পর পর আরো দেয়া হবে অথবা পাকস্থলী থেকে সংগ্রহ করা হবে। এতে রোগীর কোন কষ্ট হবে না।

৬। পরীক্ষা শুরু হওয়ার ২½ ঘন্টা পর এই নল বের করে নেওয়া হবে। এবং এর পর রোগীকে খাবার দেওয়া হবে।

৭। পরদিন সকালে রোগীকে ৫ গ্রাম জাইলোজ নামের একটি কেমিকেল খেতে দেওয়া হবে এবং এর ১ ঘন্টা পর রোগীর কাছ থেকে ১ সি সি রক্ত নেওয়া হবে।

৮। হাসপাতাল থেকে ছুটির ২-৩ সপ্তাহ পর আপনাকে আপনার শিশু সহ আরেকবার আসার জন্য উপদেশ দেওয়া হবে, এবং সে সময়ে এই পরীক্ষাগুলি পুনরায় করা হবে।

আমাদের এই গবেষণায় অংশগ্রহণে আপত্তি থাকলে অথবা অংশগ্রহনের পর যে কোন সময় প্রত্যাহার করলেও রোগীর স্বাভাবিক চিকিৎসায় কোন প্রকার ত্রুটি হবে না।

আপনি দয়া করে এই গবেষণায় অংশগ্রহণে রাজী থাকলে নিচে স্বাক্ষর অথবা