Attachment 1.

Date 21.4.81

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Dr. P. Speelman

Trainee Investigator (if any) DC

Application No. 81-018

Supporting Agency (if Non-ICDDR,B)

Title of Study Colitis in Patients with Campylobacter, V. parahaemolyticus or Shigella-infection

Project status:
(X) 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 NA
6. Will precautions be taken to protect anonymity of subjects (Yes) No
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit a 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

81-018
recd 27/4/81

SECTION I - RESEARCH PROTOCOL

1. Title: Colitis in Patients with Campylobacter, V. parahaemolyticus or Shigella-infection

2. Principal Investigator: Dr. P. Speelman

3. Co-Investigators: Dr. R. Glass
Dr. S.Q. Akhtar
Dr. M. Islam
Dr. (to be named)

4. Starting Date: July 1981

5. Completion Date: December 1981

6. Total Direct Cost: US$ 15,612 (Budget without Personnel Services : US$10,682)

7. Scientific Program Head:

This protocol has been approved by the _____ Working Group.

Signature of the Scientific Program Head W.B. Greenough

Date 21/4/81

8. Abstract Summary:

Infection with Campylobacter is common in Bangladesh. The principal site of infection seems to be the jejunum and ileum. Sometimes however, these patients pass bright red blood in the stools, suggesting involvement of the colon. This has been confirmed in some cases by colonoscopy.

It is well known that many patients with a V. parahaemolyticus associated gastroenteritis have blood and mucus in their stools.

Shigellosis is a complex disease involving distinct organs and two distinctive clinical presentations of intestinal involvement: a small intestinal phase in which the gut secretes water and electrolyts and a

colonic phase in which the Shigella penetrate the colonic wall, producing extensive damage, leading to a dysentery syndrome.

In this study, we will try to find out how frequent these agents can be isolated from the stools of patients presenting with bloody diarrhoea. In these patients we will do radiologic and colonoscopic examinations to explore and characterize Campylobacter and V. parahaemolyticus associated colitis. The findings will be compared with those of patients with a Shigella-infection and with the findings in patients with a spastic colon syndrome.

The isolates from patients with a Campylobacter or V. parahaemolyticus infection will be tested for enterotoxin production and their invasive abilities to explore a relationship between the invasiveness of strains and rectal or colonic involvement.

9. Review:

a. Research Involving Human Subjects: _____

b. Research Review Committee: _____

c. Director: _____

d. B M R C: _____

e. Controller/Administrator: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

The main objective of this study is to find out if Campylobacter-colitis (and Vibrio parahaemolyticus-colitis) is a specific disease entity and if so to study and characterize this type of colitis. Colonoscopic appearances and mucosal biopsies will be compared with those of patients with Shigella-colitis and patients with a spastic colon syndrome.

2. Background:

Infection with Campylobacter fetus ssp. jejuni is common in Bangladesh. Blaser[1] conducted culture surveys among 3 populations.

- In Dacca Campylobacter was isolated from 5.2% of 97 individuals with clinical dysentery.
- Among 204 randomly selected patients with diarrhoea the isolation rate was 12.3%, but there was a greater representation of young children in this group.
- Among 141 healthy village children Campylobacter was isolated from 17.7% (age 1-5½ yr.).
  However only 48% of these infected children had a history of recent diarrhoeal illness, significantly greater than in matched controls.

It may be clear that - as with other intestinal pathogens - infection with Campylobacters does not always produce symptoms. Asymptomatic excretors and mild cases can be found. At the other extreme, deaths have been reported, but most of the time these were in olderly or debilitated patients, where the rate of Campylobacter was not always clear. Usually the disease consists of a selflimiting unpleasant attack of acute diarrhoea, lasting for a few days.

The principal site of infection seems to be the jejunum and ileum. Most of the evidence comes from laparotomy. Since death is rare, there is little morbid anatomical evidence available. At autopsies the jejunum and parts of the ileum were found to be haemorrhagic and congested.

Now the disease is being more widely recognized and investigated evidence is gathering that infection is not limited to the small intestine. Blaser et al[2] and Karmali et al[3] reported that respectively 60 and 92% of their patients had blood in the stools. The passage of bright red blood in the stools as the disease progresses suggests involvement of the colon and this has been confirmed in some cases by sigmoidoscopy or colonoscopy. Lambert M.E. et al[4] found proctitis in 8 out of 11 consecutive patients with diarrhoea from whose stools Campylobacter were isolated. Seven biopsy specimens were abnormal with histological changes ranging from non-specific colitis to gross colitis with goblet-cell depletion and crypt-abscess formation. Nine of the eleven patients passed blood in their stools and in all but one abdominal pain was a feature of the illness. Willoughby C.P. et al[5] described a patient in whom a Campylobacter-enteritis closely resembled ulcerative colitis on clinical, sigmoidoscopic and histological ground.

Lambert J.R. et al[6] has described a patient with a severe Campylobacter-associated diarrhoea with radiologic involvement of the ileum and the transverse colon. Therapy with erythromycin resulted in complete clinical, bacteriologic and radiologic resolution of the illness.

Also in the "Public Health Laboratory Service Series"[7] 14% of the patients with a Campylobacter-infection had blood-pus or mucus in their stools, suggesting colorectal inflammation.

Recently the important role of Campylobacter as the cause of flare-up's in inflammatory bowel disease has been mentioned by Newman[8] in a letter to the Editor.

The exact pathogenic mechanism of Campylobacter is still unclear. Probably Campylobacter is an invasive organism. Butzler[9] tested one hundred isolates of patients with a Campylobacter-infection. None of the 100 isolates showed enterotoxin activity in the adrenal cell-test for LT entero-toxin; with the infant mouse assay 16 of the 100 isolates showed evidence of ST-enterotoxin activity.

The ability of enteroinvasiveness was tested by inoculating chicken embroy's with the test strains. All 5 strains appeared to be invasive.

Butzler concluded that Campylobacters are pathogenic mainly by virtue of a direct invasive ability and that enterotoxin production is a feature of only a few starains.

Non-Agglutinable Vibrios

Vibrio cholerae O-group I has historically been the vibrio of greatest interest to clinicians. Other vibrios were simply dismissed as non-agglutinable vibrios or non-cholera vibrios. Later it became apparent that these vibrios included several species that are often pathogenic for humans and that have distinct clinical features. These species now include V. parahaemolyticus, V. vulnificus, V. alginolyticus, group F vibrios etc. etc..

From November 1977 through April 1978 a study was performed in the CRL by Spira et al[10] to define detailed clinical and laboratory features of diseases due to non-O-group I agglutinating V. cholerae, including V. parahaemolyticus. They screened all patients admitted to the Treatment Centre by darkfield microscopy. Only enriched darkfield results agreed with bacteriological culture.

Out of 700 patients 77 cases were positive in both methods; twenty-one of these patients had V. para that means 2½% of all screened patients, 14 patients had a non-O-group I V. Cholerae. In these two groups the main symptoms were vomiting, abdominal pain, fever and muscle cramps. Fecal red blood cells were observed significantly more often in V. para cases. Ten cases had 6-10 or more RBC/hpf; of these cases 9 had a history of bloody stool (that means 45% of all V.para patients). So, colitis seems to be rather common in patients with a V. para infection.

The pathogenicity of V. para is still not clear. In 1968, Sakazaki et al[11] reported that the ability of V. parahaemolyticus to cause hemolysis on Wagatsuma agar (the Kanagawa phenomenon) was associated with gastro-intestinal illness. This has been confirmed by others. Spira studied 27 strains of V. para isolated from patients with a diarrhoeal illness. He could <u>not</u> demonstrate a LT or ST like toxin.

Shigella-colitis

In both man and monkey, oral infection with Shigella flexneri generally results in the onset of fever and watery diarrhoea within 24 to 72 hours. In many instances this is followed by the dysentery syndrome, including abdominal cramps, tenesmus and bloody mucoid stools. In severe cases the watery diarrhoea phase may be obscured, mild cases on the contrary may never escalate to dysentery.

In dysentery cases, the inflammation involves the large intestine and occasionally the terminal ileum. There is discrete serpiginous ulceration with an intervening mucosa which is granular and haemorrhagic.

Whenever there is dysentery, the colon is markedly inflamed and many invading bacteria are present[12, 13]. In experimental infection, dysentery bacilli penetrate the intact epthelium in course of a few hours. Inflammatory changes follow and include the formation of crypt abscesses indistinguishable from those seen in ulcerative colitis.

Electron microscope studies on rectal biopsy material failed to reveal any specific changes. From studies performed by Koster et al[14] on the haemolytic-uraemic syndrome complicating shigellosis in Bangladeshi children it is known that severe colitis is frequently associated with the development of haemolytic anaemia.

Rationale:

Bloody diarrhoea is a common condition in Bangladesh, in many cases caused by Shigellae or Amoebae. However, in several cases no cause can be found. The ICDDR,B (The International Centre for Diarrhoeal Disease Research, Bangladesh) is in an unique position to investigate the role of Campylobacter and Vibrio parahaemolyticus in causing colitis and bloody diarrhoea and to characterize these forms of colitis, because of the relatively common nature of the problem and having expertise in the Centre and also the necessary facilities and equipment.

B. SPECIFIC AIMS

1. To explore how frequent Campylobacter ssp. jejuni and Vibrio parahaemolyticus can be isolated from the stools of patients presenting with bloody diarrhoea and to study these patients extensively, including radiology and endoscopy of the colon with biopsies if mucosal lesions are present.

2. To explore if the isolates from these patients produce enterotoxin and have invasive abilities and to find out if there is a relationship between the invasiveness of strains and rectal or colonic involvement.

C. METHODS OF PROCEDURE

Two hundered adult patients, 16 years of age or older, male and female, presenting at the outpatients department of ICDDR,B with bloody diarrhoea*, can participate in the study. It is anticipated that the illness of these patients will be primarily:

- Shigellosis
- Amoebic dysentery
- Campylobacter enteritis / colitis
- Vibrio parahaemolyticus enteritis / colitis
- Non-Shigella dysentery

From these patients presenting with bloody diarrhoea a stoolsample will be taken to check for macroscopic or microscopic blood. If blood is present, they are eligible for this study. No more than 2 patients a day can be admitted to the study-protocol. The first two, presenting on that day, will be selected.

After admission (day 1) a standardized medical history will be taken and physical examination will be performed. The following laboratory investigations will be done:

- blood: CBC/antibodies/alfa-1-antitrypsin
- urine: analysis
- stool: 3 specimens 1 x ME; 3 x culture (if positive for amoebae stool for amoebic culture and parasite antigen)
- saliva

Treatment will be given according to the best clinical judgement. However no antibiotics will be given till the result of the stool-culture is known unless the clinical condition of the patient requires antibiotic treatment.

*duration of bloody diarrhoea: no longer than 7 days

On day 2 no special studies will be done.

On day 3 the result of the stool-culture will be known. The culture-result can be:

1 positive for Shigella

2 positive for Campylobacter or V. para

3 negative

4 mixture

If there are no contraindications all patients in group 2 will have a fiberoptic sigmoidoscopy / colonoscopy at day 4 after proper cleansing the colon with enema's of isotone saline. If colonic lesions are detected, biopsies will be taken to learn the histologic appearances of these abnormalities.

About 15 patients in group 1 will have the same examination in order to compare the abnormalities in the colon with those in patients with Campylobacter or Vibrio para. We will try to select patients of the same age and sex and with more or less the same duration of illness. Patients with serious complications or severe malnutrition will not be eligible for this examination.

Fifteen Bangladeshi patients with spastic colon syndrome will serve as a control group. I have already examined several Bangladeshi patients with colonoscopy in order to exclude serious colonic diseases. However, these patients proved to have a spastic colon syndrome. I expect to see more of these patients in the near future.

All these patients will have an upper G.I. series on day 5 in order to get information about lesions in the terminal ileum and the R site of the colon.

Hereafter the clinical condition of the patient will be re-evaluated to decide if the patient is allowed to go home.

Patients in group 3 only will be treated according to the best clinical judgement and will be discharged as soon as the clinical condition allows this. Also those patients with a proven Shigella infection who are not selected for further examination will be discharged as soon as the clinical condition allows this.

Campylobacter and V. parahaemolyticus strains will be stored for examination of invasiveness (Sereny-test) and toxin-production (ileal loops, CHO-cells, infant mouse assay). Correlations will be sought between the results of these tests and the clinical findings in the patients.

Treatment

Patients will be treated according to the best clinical judgement. If indicated, antibiotics will be prescribed.

Shigella-infections: first choice ampicillin - 2 g per day in adults for five days.
(second choice - Trimethoprim-Sulfamethoxazol)

Campylobacter-infections: first choice Erythromycin - 500 mg b.d for adults for five days (second choice Gentamycin or Chloramfenicol)

Vibrio parahaemolyticus-infections: according to sensitivity

Amoebic dysentery: Metronidazol 800 mg t.d. for 5 days, followed by diiodohydroxyquinoline for 10 days.

D. SIGNIFICANCE

This study will provide valuable information about the possible role of Campylobacter and V. parahaemolyticus in causing acute colitis We will be informed about the abnormalities in the colon during a Campylobacter or V. parahaemolyticus infection and perhaps a relation with ability of invasiveness of these strains will be found.

E. FACILITIES REQUIRED

1. Office space is already provided; in the study ward a curtain has to be made to provide a "room" for the colonoscopies.
2. Laboratory space is already provided.
3. Hospital resources: about 200 patients will be hospitalized during a period of 3-7 days.
4. The laboratory for histopathology will be used for processing the biopsies; Dr. M. Islam and Mrs. S. Pashi will be in charge of this part.
5. Animal resources are required for toxin-testing (ileal loops, CHO-cell-tests, infant mouse assay) and tests for enteroinvasiveness (Sereny-test)
6. Logistic support: a study nurse has to assist during colonoscopies. Nurses are required to take care for the patients in the study ward.
7. Major items of equipment: a colonoscope with cold light supply is available from Dr. Speelman. A new colonoscope has been ordered from Japan.

REFERENCES

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   Isolation of Campylobacter fetus ssp. jejuni from Bangladesh children - J. Clin. Microbiol 1980 12(6) 744-747

2. Blaser M.J., Berkovitz I.D., LaForce F.M. et al
   Campylobacter enteritis : Clinical and Epidemiologic Features - Annals of Internal Medicine 1979 91 179-185

3. Karmali M.S. and Fleming P.C.
   Campylobacter enteritis in children - J. of Paediatrics 1979 94 527-533

4. Lambert M.E., Scholfield Ph.F., Irouside A.G. et al
   Campylobacter colitis - British Medical Journal 1979 1 857-859

5. Willoughby C.P., Piris J. and Truclove S.C.
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6. Lambert J.R., Tischler M.E., Karmali M.A. et al.
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7. Public Health Laboratory Service Series
   British Medical Journal 1978 1 1357

8. Newman A., Lambert J.R.
   Campylobacter jejuni causing flare-up in I.B.D.
   - Lancet 1980 2 919 (letter)

9. Butzler J.P. and Skirrow M.B.
   Campylobacter enteritis - Clinics in Gastroenterology 1979 Vol.8 No.3 737-767

10. Spira W.M., Daniel R.R., Ahmed Q.S. et al.
    Clinical features and pathogenicity of O group I nonagglutinating V. cholerae and other vibrios isolated from cases of diarrhoea in Dacca

11. Sakazaki R., Tamura K., Kato T. et al
    Japan, J. Med. Sci. Biol. 1968 21 325-331

12. Takenchi A., Farmal S.B. and Sprinz H.
    Exp. Acute colitis in the Rhesus monkey, following peroral infection with Shigella flexneri - Am. J. of Pathology 52 503-529

13. Rout W.R., Formal S.B. Giannella R.A. et al
Pathophysiology of shigella diarrhoea in the Rhesus monkey Gastroenterology 68 270-278

14. Koster F., Levin J., Walker L. et al.
Hemolytic-uremic syndrome after shigellosis
New Engl. J. of the Med. 1978 298 927-933

ABSTRACT SUMMARY

1. Two hundred adult Bangladeshi patients, male and female, will participate in this study. Children will be excluded because we do not have the proper equipment for performing sigmoidoscopy/colonoscopy in children.

2. Blood will be taken from the patients by venapuncture for different investigations. In experienced hands a barium enema is without substantial risk for the patients. Sigmoidoscopy/colonoscopy is a routine procedure in western countries. In skilled hands and after adequate preparation and sedation of the patient this procedure is unconvenient but well tolerable. Diagnostic colonoscopy has a complication rate of 0.24% (bleeding, perforation). Other methods to obtain the wanted information are not available.

3. All patients will have complete histories taken and physical examination Bloodgroup CBC and platelets-counts will be done. When a contraindication is found for one of the investigations the procedure will be abandonned. Only adult patients are involved. However when a complication occurs, adequate treatment facilities including surgery will be arranged.

4. All clinical records will be maintained in locked file in the clinical office. All specimens for research will be coded and the link between specimen and person will be kept in a locked file.

5. Signed informed consent will be obtained.

6. Medical histories will be obtained.

7. Dysentery is a common condition in Bangladesh, in many cases caused by Shigellae or Amoebae. However in several cases no cause can be found. The individual patient will benefit from this study by receiving a correct diagnosis and adequate treatment for his dysentery. The society in general will benefit from the knowledge acquired by this study protocol, about the role of Camylobacter and V. parahaemolyticus in acute colitis. The knowledge obtained by this study can help many patients with dysentery and will outweight the small risks of this study.

8. The planned research will use clinic records, blood, stool and mucosal biopsies.

SECTION III - BUDGET

A. DETAILED BUDGET

1. **Personnel Services:**

	Position	%Effort	Taka	Dollar
Dr. P. Speelman	Investigator	20	-	2,500
Dr. R. Glass	Co-Investigator	-	-	-
Dr. S.Q. Akhtar	Co-Investigator	5	1,200	-
Dr. M. Islam	Co-Investigator	?	-	-
Dr. (to be named)	Co-Investigator	50%	10,000	-
To be named	Nurse	100%	12,000	-
To be named	Tec.Clin.Pathol.	10%	1,200	-
To be named	Tec.Microbiology	30%	6,000	-
Mrs. S. Pashi	Res.Officer (Histopathology)	50%	8,500	-
		Sub Total :	38,900	2,500

2. **Supplies and Materials:**

a. Clinical supplies (needles, medication)			-	500
b. Lab supplies (media, reagents)			-	200
c. Lab tests:				
CBC	200 x Tk.8	1,600		
Stool ME	200 x Tk.5	1,000		
Stool culture	200 x 3 x Tk.29	17,400		
Sereny tests	25 x 2 x Tk.40	2,000		
Ileal loop	25 x 2 x Tk.150	7,500		
ST & LT	25 x 2 x Tk.20	1,000	30,500	
		Sub Total :	30,500	700

3. **Equipment:** 0

4. **Patients Hospitalization:**

200 patients x 3 days x Tk.150	90,000		
30 patients x 4 days x Tk.150	18,000	108,000	-
	Sub Total :	108,000	0

5. **Out-patient Care:** Sub Total : 1,000 0

	Taka	Dollar
6. ICDDR,B Transport:		
Mileage 200 x Tk.5	1,000	-
Sub Total :	1,000	0
7. Travel & Transportation: 0		
8. Transportation of Things: 0		
9. Rent, Communications, Utilities: 0		
10. Printing/Xerox:	-	1,000
Sub Total :	0	1,000
11. Other Contractual Services: 0		
12. Construction, Renovation, Alterations :	-	200
Sub Total :	0	200
Grand Total :	179,400	4,400
Total US Dollar :	15,612	

Budget without Personnel Services - 15,612
4,930-
US$: 10,682

B. BUDGET SUMMARY

		US Dollar
1.	Personnel Service	4,930
2.	Supplies & Materials	2,606
3.	Equipment	-
4.	Patients Hospitalization	6,750
5.	Out-patient Care	63
6.	ICDDR,B Transport	63
7.	Travel & Transportation	-
8.	Transportation of Things	-
9.	Rent,Communications,Utilities	-
10.	Printing/Xerox	1,000
11.	Other Contractual Servies	-
12.	Construction, Renovation, Alteration	200
	Grand Total	: 15,612

(Conversion rate - US$ 1 = Tk.16)

PERMISSION FORM

Dysentery is a very common and serious disease in Bangladesh. Certain bacteria and amoeba can cause dysentery, that means diarrhoea with blood and/or mucus. However, in a number of cases no cause for the dysentery can be found. Since a few years we know that there are also other (new) bacteria, which can cause dysentery.

In this study we will investigate the role of these bacteria as a cause of bloody diarrhoea. During this study we will give you treatment according to the best clinical judgement.

If you agree to participate in this study, we will keep you in the hospital for a period of 3-6 days.

On the first day we take some blood, urine and stools. If the culture of your stool is positive for one of these bacteria, we will perform a colonoscopy, that means we will pass a tube with a diameter of about 1 cm in your bowels by the anal route. To minimize your discomfort we will give you a sedative if required. If there are abnormalities in your large bowel, we will take a very small biopsy of your bowel tissue. This will not hurt you at all. This procedure has been performed on many patients without serious complications. It is now routinely done in the developed countries for diagnostic and therapeutic purposes.

The next day, we will make X-Rays of your bowels. For this investigation you have to drink a barium-solution. This investigation will not cause any discomfort. Hereafter your clinical condition will be checked again. If you are in good condition, you may go home.

We will ask you to come back 2 weeks after discharge, for blood-investigation. For this occasion travel expenses will be reimbursed.

You do not have to join the study. If you decide not to join, you will still be eligible for care at ICDDR,B. You may also decide to withdraw after entering the study and this will not affect any medical care you might require now or later on.

(I agree that the above study has been explained to me. I have understood it, and I agree to participate)

Signature: _____

Thumb impression :

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র

বাংলাদেশ

সম্মতি পত্র

==========

বাংলাদেশে আমাশা/রক্ত আমাশা/রক্ত সহ উদরাময় একটি অতি সংক্রমক ও মারাত্মক ব্যাধি। অনেক সময় আমরা এই ব্যাধির কারণ খুঁজে পাই - আমার অনেক সময় ব্যর্থ হই। কয়েক বৎসর যাবৎ নানারূপ অনুসন্ধানের পর নতুন কয়েকটি রোগজীবাণু এই সব ব্যাধির কারণ বলে ধরা পড়েছে।

এবার আমাদের এই গবেষণায় উক্ত জীবাণুগুলি কি করে নির্মূল করা যায় তার জন্য এক বিশেষ কার্যকরী অনুসন্ধান চালাচ্ছি। আপনারা যারা আমাশা/রক্ত আমাশা/রক্ত সহ উদরাময় ব্যাধিতে আক্রান্ত তারা যদি কেউ আমাদের এই গবেষণায় অংশগ্রহণ করতে ইচ্ছুক হোন তবে আপনাকে আমরা এই ক্লিনিকে ভর্তি করে নেবো এবং নিম্নলিখিত উপায়ে চিকিৎসা করবো যাতে আপনি সম্পূর্ণরূপে সুস্থ্য হয়ে উঠতে পারেন। আপনার অসুখের অনুসন্ধান পর্বের জন্য ৩ দিন থেকে ৬ দিন মাত্র সময় লাগবে এবং সেই সময় এইখানে থাকার সুযোগ পাবেন।

— প্রথম দিন আপনার রক্ত, পায়খানা ও প্রস্রাব পরীক্ষা করা হবে। যদি এই সকল পরীক্ষায় আপনার ব্যাধির কারণস্বরূপ কোন রোগ জীবাণু ধরা পড়ে তবে কোনরকম প্রক্রিয়া দ্বারা (একটি খুবই সরু আকারের নল পায়খানার রাস্তায় প্রবেশ করিয়ে পেটের ভিতরের ছবি নেওয়া এবং বায়োপসির জন্য কিছু টিসু সংগ্রহ করা) আমরা আপনার সুচিকিৎসার জন্য একটি অনুসন্ধান চালাবো। এই প্রক্রিয়া চলাকালীন আপনি যাতে অসাচ্ছন্দ বোধ না করেন তার জন্য কিছু ঘুমের ঔষধ আপনি দরকার মত গ্রহণ করতে পারেন। রোগ পরীক্ষার জন্য এই কোলনস্কপি প্রক্রিয়াটি পৃথিবীর সব উন্নত দেশগুলোতে আজকাল বহুলরূপে ব্যবহৃত হচ্ছে।

অঃপৃঃদ্রঃ

এর পরদিন আপনাকে বেরিয়াম মিল খেতে দিয়ে আপনার পেটের এক্সরে নেবো। তারপর আপনার শারীরিক সব কিছু পরীক্ষার পর যদি সুস্থ বোধ করেন তবে বাড়ী চলে যেতে কোন বাধা থাকবে না।

দুই সপ্তাহ পর আবার একবার রক্ত পরীক্ষার জন্য আপনাকে আমাদের ক্লিনিকে আসতে হবে এবং এরজন্য যাতায়ত খরচ আমরা আপনাকে দিয়ে দিবো।

আপনি এই গবেষণায় অংশগ্রহণ করতে না চাইলেও এখনকার সুচিকিৎসা আপনাকে যথারীতি দেওয়া হবে। যদি অংশগ্রহণ করার পর আবার কোন কারণে এই গবেষণা ত্যাগ করতে চান তবুও আমাদের কাছ থেকে চিকিৎসার সব রকম সুযোগ সুবিধা পাবেন।

— আমাকে এই গবেষণার বিষয়বস্তু ভাল করে বুঝিয়ে বলা হয়েছে এবং এখন আমি স্বেচ্ছায় এতে অংশ গ্রহণে ইচ্ছুক —

স্বাক্ষর----------

টিপ সহি----------