REVIEW BOARD ON THE USE OF HUMAN SUBJECTS, ICDDR,B.

Principal Investigator Dr. G.H. Rabbani
Application No. 79-007

Title of Study "Effect of Chlorpromazine (Z) on oral rehydration therapy in acute diarrhea".

Trainee Investigator (if any)______________________
Supporting Agency (if Non-ICDDR,B)______________________
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).

5. Will signed consent form be required:
   (a) From subjects [ ] Yes [ ] No
   (b) From parent or guardian [ ] Yes [ ] No
   (c) 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 Review Board:
   ( ) 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 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. A description 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 Board for review.

We agree to obtain approval of the Review Board on the Use of Human Subjects for any change involving the rights and welfare of subjects before making such change.

G.H. Rabbani
Principal Investigator

Trainee: ____________________________
SECTION I - RESEARCH PROTOCOL

1) Title: Effect of Chlorpromazine (CPZ) on oral rehydration therapy in acute diarrhoea.

2) Principal Investigator: Dr.G.H.Rabbani
   Co-investigators: Drs. Greenough, Holmgren, Molla, Mamtaz & Shafiq.

3) Starting Date: 15 August 1979

4) Completion Date: 15 October 1979

5) Total Direct Cost: TK. 87,975 $1210

6) Availability of funds:
   a) Scientific Director's Remarks:
   b) Controller's Remarks:

7) Abstract Summary: As chlorpromazine (CPZ) has effectively inhibited fluid secretion in adult cholera patients, we propose to investigate whether CPZ can be used to reduce the failure rate in oral rehydration therapy by reducing the purging rate in acute diarrhoea patients. This will be done as a double blind randomized trial involving 110 hospitalised, male, diarrhoea patients with moderate to severe dehydration. Females and children weighing less than 10 kg will be excluded. All patients will be randomly assigned into a treatment or a same control group (55) following a table of randomized numbers. All patients will be initially rehydrated using standard IV fluid. In the treatment group Chlorpromazine will be given by mouth at a dose of 4mg/kg and a placebo will be similarly given in the control group. Thereafter in all patients hydration will be maintained using same oral fluid until the diarrhoea stops. 8 hourly intake and output chart will be maintained and rectal swabs will be taken for detection of V. Cholerae, toxigenic E. coli, Rota Virus, Shigella and Salmonella. Data on both the groups in relation to hydration will be compared.
8) **Reviews:**

a) Research Involving Human Subjects: 

b) Research Committee: 

c) Director: 

d) EMRC: 

e) Controller/Administrator: 
SECTION 11 - RESEARCH PLAN

A. INTRODUCTION

1. Objectives:

   a) To evaluate the effects of a single dose of chlorpromazine (CPZ) in reducing the failure rate of oral therapy in acute diarrhoea.

   b) To determine whether the observed fluid inhibitory effect of chlorpromazine also extends to non-cholera diarrhoea.

   c) To determine the response of chlorpromazine in acute diarrhoea in children.

2. Background:

   As chlorpromazine effectively inhibited fluid secretion in adult male cholera patients studied at this laboratory (66 + 5% stool reduction in CPZ treated patients as compared to 26 + 9% reduction in a matched control group: Rabbani, Greenough, et al, Lancet, 24 Feb 1979), we consider that incorporation of chlorpromazine (CPZ) with oral fluid therapy may be of worth trying to reduce the failure rate of orally treated diarrhoea patients.

   The successful role of oral rehydration therapy in the treatment of acute dehydrating diarrhoeas has increasingly been demonstrated over the past decade. Considerable hospital and field experience has been gained in the use of glucose-electrolyte oral rehydration solution as a simple treatment for dehydration in acute diarrhoeal diseases (Cash 1970, WHO, DDC, 79; Pierce 1968, Hirschhorn 1968 and Mahalanabis 1974). Inspite of such remarkable efficacy of oral solution in diarrhoea yet certain percentage of patient would fail to keep up hydration when maintained on oral fluid. Failure is considered when the patient is unable to maintain hydration with oral fluid and subsequently develops clinical indication for administration of IV fluids.

   The WHO oral formulation currently in use has a failure rate of 10-20%. In Dr. D. Sack's Sucrose-Glucose study in children with cholera a failure rate of 23-27% was seen. Dr. Palmer has reported a similar rate of failure of 23-24% in adult cholera in 1977 from Dacca (Palmer et al 1977). Oral hydration study conducted with Labon-gur solution had a failure rate of about 30% in children, though a significantly higher rate of success is achieved in case of adults (Dr. R. Islam, personal communication). Rice-Starch oral hydration study also met a failure rate
of more than 10% in young adults (Dr. M. Molla, unpublished data). It has been observed in all these studies that the primary determinant of success of oral fluid irrespective of the formulation (sucrose or glucose) was the purging rate. Patients who had a high purging rate are most difficult to be managed on oral therapy and subsequently need IV fluid for rehydration.

So in the light of foregoing discussion it can be concluded that the purging rate appears to be most crucial and an important primary determinant of success of oral fluid therapy. Therefore, anything which can reduce the purging rate would almost certainly decrease the number of failure of patients maintained on oral therapy alone. With this view in mind pharmacologic agents have been sought to reduce the fluid loss and among many other agents tested chlorpromazine appears to provide most encouraging results and proved to be a useful antisecretory agent in diarrhoea.

The effect of adding CPZ to the conventional treatment of cholera (i.e. fluid plus tetracycline) may either be additive or synergistic, since vibriocidal and antitoxic effects are combined. This is more likely to bring about a net reduction in the stool output, specially when the secretion is known to be mediated by c-AMP Adenylate cyclase activation system.

As chlorpromazine (CPZ) has recently been shown by us to reduce stool output by 66 percent over a period of 32 hours following an oral dose, we anticipate that giving CPZ and then continuing oral solution it may be possible to keep up hydration thereby obviate the need for IV fluids and secondarily reducing the failure rate of oral therapy.

WHO on chlorpromazine: In a recent meeting of WHO Diarrhoeal Disease Cont. Proc. in New Delhi (30 Oct 1978) a group of international experts have strongly emphasized the need to explore the fluid inhibitory drugs (i.e. nicotinic acid, aspirin and indomethacin) and have specifically stated chlorpromazine as encouraging and should go for further research.

Safety of Chlorpromazine: In our clinical trial with chlorpromazine at a dose of 200 mg PO/IM (4mg/kg), we were unable to demonstrate any significant changes in blood pressure, radial pulse, respiratory rate and level of consciousness. Patients become somewhat drowsy but were easily aroused. No other untoward reactions were seen.

Chlorpromazine: Mechanism of action: Recently Holmgren (1978) and Lonnroth's (1977) studies in experimental mice have clearly demonstrated the reversal of cyclic AMP mediated intestinal secretion and inhibition of cholera toxin induced hypersecretion by chlorpromazine. Currently available data supports the hypothesis
In severely dehydrated patients initial fluid deficit will be replaced immediately using standard IV solutions (70 ml/kg). IV will then be stopped and no further IV fluid will be given thereafter unless a hydration failure is considered on clinical and laboratory findings, in which case the subject will be dropped from the study. A dose of CPZ (4mg/kg) will be administered orally in liquid form at the time of stopping IV, or immediately before beginning oral therapy. Subsequently patient's hydration will be maintained by giving oral fluid (30 ml/kg) at lib to complete the hydration.

Hydration in patients with moderate dehydration will be started with and maintained on oral fluid alone and no IV fluid will be given initially. Similarly a single dose of CPZ will be given PO at the time of starting oral therapy. Maintenance of replacement therapy will continue until the diarrhoea stops. Patients will be considered to have their diarrhoea stopped if no watery stool is passed during the preceding 24 hours.

Patients with mild degree of dehydration will similarly be dealt with as those of moderate dehydration.

Tetracycline: Tetracycline in the usual dose (250 or 500 mg PO/6h) will be given to all adult patients who has a vibrio positive stool either on culture or dark field microscopy. Vibrio positive children will also be treated with appropriate doses of tetracycline. No routine treatment with tetracycline will be given to non-cholera diarrhoea patients.

ORAL FLUID: Oral fluid to be given will be prepared at ICDDR,B biochemistry laboratory following the WHO recipe containing glucose (sucrose will not be used) and will have the following composition:

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<td>KCl</td>
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<td>Glucose</td>
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<td>Na⁺</td>
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<td>Cl⁻</td>
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<td>HCO₃⁻</td>
<td>30 mEq/L</td>
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<tr>
<td>Glucose</td>
<td>111 mEq/L</td>
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</table>

Clinical and Laboratory Data:

During the initial period (first 4 hours after admission) intake and output records will be maintained every 4 hours and then every 8 hours until the diarrhoea stops. Mothers and the Ward staffs will be instructed to encourage feeding oral fluid to the child. Frequent administration of small amount of solution will be encouraged to avoid vomiting.

Dose of chlorpromazine: Single dose of CPZ (4 mg/kg) will be administered by mouth to all patients after initial rehydration by IV fluid, i.e. before beginning oral fluid therapy. CPZ will be given in syrup form.
On Admission, general clinical examination will be done on all patients to assess the initial dehydration. If complications such as tuberculosis, pneumonia or severe malnutrition is also present the patient will be excluded. Clinical exam especially looking for the signs of dehydration will be repeated at 4 hr, 8 hr, 16 hr, 24 hr and then every 8 hr until the diarrhoea stops.

Admission data on serum electrolytes, blood sp. gr. haematocrit value, urine analysis, complete blood count will be done. For the assessment of hydration status finger blood specific gravity will be repeated every 8h for the first 24 hours (at 8, 16 and 24 hour) and serum electrolytes will be repeated at 8h and then every 24 hour till discharged. Stool and urine volume will be measured at 4 hourly intervals and cumulative volume records will be kept.

Rectal Swabs: Rectal swabs will be taken on admission and will be plated on Mac Conkey's agar, SS agar, Monsur's (SP) and TCBS. Agents looked for will include V. Cholerae, enterotoxigenic E. coli, rata virus, Shigella and Salmonella. From the Mac Conkey's plate 5 lactose positive colonies that are typical of E. coli will be picked and stored in blood agar slant for testing LT by using either Chinese Hamster Ovarian Cell (CHO) assay or YI adrenal cell assay. Two of the colonies will be tested for ST by infant mouse assay. One swab in PBS (pH 7.4) will be preserved frozen until they can be tested for rota virus antigen by ELISA assay.

Patients will be discharged when diarrhoea stops. Treatment for intestinal ova and parasites will be given (if present) at the time of discharge.

Treatment Failure:

If clinical indications to resume intravenous fluid develop at any time during oral medication it will be judged as a failure to oral therapy and the patient will then be dropped from the study. Decision to resume IV fluid will be based on objective criteria: a) a return of clinical signs of dehydration including loss of body weight, b) persistent vomiting preventing the use of oral fluid, c) an increase in plasma sp. gr (more than 1.0300).

D. SIGNIFICANCE

The idea is to improve the effectiveness of present form of oral therapy by overcoming one of its important shortcomings (i.e. failure in high purging rate) by the addition of a simple and inexpensive drug chlorpromazine.
E. FACILITIES REQUIRED

1) Office Space: The present study room office will be used by Drs. Rabbani, Montaz, and Shafiq. No extra space is necessary.

2) Laboratory Space: ICDDR(B) existing lab will be utilized.

3) Logistic Support: Data processing and computer support from statistics branch will be required.

F. COLLABORATIVE ARRANGEMENTS

Consultation by correspondence will be maintained with Prof. J. Holmgren in Sweden. No cost in involved.

Data Analysis: After collection of data, it is anticipated that the following analysis and others will be performed:

1) Failure rate of oral hydration in CPZ treated and Placebo (control groups will be compared to see the effect of Chlorpromazine.

2) Percent of stool reduction in treated group will be compared to that of control group to determine the antisecretory action of CPZ.

3) To determine that CPZ is also effective in non-Cholera diarrhea, patients with different etiologies (E.coli, Rota virus etc) will be compared to cholera with respect to fluid inhibition.

In addition to all these the two groups (CPZ treated and controls) will be compared to determine if there is any significant difference in relation to the following variables:

a) Pretreatment clinical data like degree of dehydration, age, sex, duration of diarrhea etc to see that the groups are comparable.

b) Rate of purging and rate of rehydration.

c) Rate of oral intake.

d) Volume of IV fluid needed in failure cases. 

e) Serum Electrolytes (Na+, K+, Cl, CO_2) and other Laboratory data.

Statistical Principle:

Data collected will be transferred on to the IBM cards through intermediate coding and analysis will be performed by computer. The parameters of this
study will mainly be the rates, such as failure rate, rehydration rate etc. Comparison of these rates will be made using appropriate statistical principles such as Chi square, Student's t test and analysis of variance.

Abstract Summary:

This study will be conducted on 120 hospitalized, male diarrhoea patients weighing 10 kg or more. The patients will be admitted into the hospital for 3-5 days and will be discharged when diarrhoea stops. The stool reducing effect of chlorpromazine has been determined in adult cholera patients earlier. This study has been designed to determine the drug's response in children and also in diarrhoea other than cholera. Children have been included in this study because they constitute the high risk population in the community and also have high mortality and morbidity from acute infective diarrhoeas. Whether chlorpromazine can effectively turn off fluid secretion in children without any adverse effects - this information in itself would be important to know.

2. All diarrhoea patients will initially be fully rehydrated using standard intravenous fluids before any chlorpromazine is administered. This is expected to prevent the likelihood of any hypotension or cardiovascular reaction when CPZ is given. There will be no other physical, social or psychological risk to the patient.

3. Not applicable.

4. Data collected will be computerized and confidentiality will be maintained by locking the files in the cabinet until the completion of the study. All data will be abbreviated and will be published without reference to the subject's name and identity.

5. Informed consent (signed or thumb print) will be obtained from all adult patients and in case of minor subjects the same will be obtained from the parents or legal guardian. There is no procedure in this study which may unmask the privacy of the subject.

6. Interview to be taken only relate to history of illness and is needed only for clinical management of the disease. Five minutes would be enough to take such a clinical history.

7. Direct benefit to the subject would include a more efficient treatment of his illness and a quick recovery than usual duration. Patients with
cholera will be treated with Tetracycline to enhance recovery and vibrio clearance. The indirect and long term benefit of this study would be to provide a simple form of treatment of acute dehydrating diarrhoeas with oral fluid having much improved efficacy and very little failure. This will have more practical value so far as the mass treatment of rural communities are concerned.

8. New data will be generated from the study patients. No pre-existing data or hospital records will be utilized.
BIBLIOGRAPHY


9. Dr.M.Molla: Rice-Starch oral hydration study; ICDDR(B), 1979, Personal communication.


SECTION III - BUDGET

A. DETAILED BUDGET

I. PERSONNEL SERVICES

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Percent of effort</th>
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<th>Project Requirements</th>
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<td>30%</td>
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<td>Dr. Shafiq</td>
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<td>Dr. Al Mahmood</td>
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SUB TOTAL Tk. 12,085 $ 900

2. SUPPLIES AND MATERIALS

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SUB TOTAL Tk 5500 $ 310

3. EQUIPMENT

4. PATIENT HOSPITALIZATION

Number of patient days @ Tk. 150/day:

SUB TOTAL Tk. 67500 $ -

5. OUTPATIENT CARE

6. ICDDR(B) TRANSPORT

7. TRAVEL AND TRANSPORTATION OF PERSONS

   LOCAL TRAVEL

   INTERNATIONAL TRAVEL

8. TRANSPORTATION OF THINGS
9. RENT, COMMUNICATION AND UTILITIES

10. PRINTING AND REPRODUCTION

11. OTHER CONTRACTUAL SERVICES

12. CONSTRUCTION, RENOVATION, ALTERATIONS

LABORATORY TESTS

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SUB TOTAL                   | Tk. 2890    | 00        |

B. BUDGET SUMMARY

1. Personnel                Tk. 12,085  $ .900
2. Supplies & Materials     Tk.  55,00   $ .310
3. Equipment                ----        ----
4. Hospitalization          Tk.  67,500  ----
5. Laboratory Tests         Tk.  2890    ----
6. Outpatient               ----        ----
7. ICDDR(B) Transport       ----        ----
8. Transportation of things ----        ----
9. Rent/Communication       ----        ----
10. Printing/Reproduction    ----        ----
11. Contractual Services    ----        ----
12. Construction            ----        ----

GRAND TOTAL                 Tk. 87,975  $ .1210

(Conversion Rate Tk.15.00 equals $.1.00)
Chlorpromazine-Oral hydration study

(CONSENT FORM)

This international center is actively working in the field of diarrhoeal diseases to improve and simplify the treatment of cholera and non cholera diarrhoeas. It has now been increasingly recognized that replacement of fluid and electrolytes is the most effective form of treatment in all dehydrating diarrhoeas. Fluid and electrolyte replacement can be achieved fairly easily by giving electrolyte containing solutions by mouth.

In this present study we will utilize the fluid inhibitory effect of a drug "Chlorpromazine" given in a single stat dose at the beginning of oral therapy which we expect will greatly obviate the need for IV fluid thereby reducing the rates of hydration failure. This drug has been experimented by us in this laboratory and proved to be an effective antisecretory agent in cholera. Chlorpromazine has slight sedative effect and very negligible lowering effect on blood pressure. When ingested at a dose of 2 mg/kg it is capable of making you or your child a little sleepy or drowsy. Otherwise this drug is quite free from any other injurious side effects.

If you or your child is sick with acute diarrhoea you can participate in this study. If you decide to participate in this study you can expect the following:

1). You/your child will be admitted into the hospital and will stay until the diarrhoea is stopped.

2). Chlorpromazine in a dose of 2 mg/kg will be administered to children and adults by mouth in a liquid form after initial rehydration with IV fluids. This is a palatable syrup and will be happily accepted by the children.

3). After the dose of chlorpromazine IV will be removed and hydration will be carried out by giving oral fluid of standard composition recommended by the World Health Organization (WHO).

4). If you/your child have cholera then it will be treated with either tetracycline or doxycycline following standard dose.

5). You will have complete freedom to drop yourself/your child from the study at any time you wish. In such case regular treatment will not be refused and you will not be penalized in any way.

6). 2-3 cc venous blood will be drawn 3 times during hospitalization for lab tests.

If you have understood all these and decide to participate, please sign below.

Date: ____________________ Signature: ____________________
ਅਕਾਲਵਾਕਸ ਜਿਆਦਾ ਸ੍ਰੋਤਾਂ ਕੇਂਦਰ, ਕੈਦਰਾਚਾਰ

(ਜਾਨਵੀਰ ਨਾਂ)

ਇਸ ਲਈ ਸਾਬਕਾ ਕਲਾਸ ਸੁਧਾਰਨ ਕੰਮ ਕਰਨਾ ਚਾਹੁੰਦਾ ਸੀ। ਇਸਨੂੰ ਸਿਰਫ ਕਰਨ ਦੀ ਪ੍ਰੀਤ ਨਾਲ ਹੇਠ ਸੋਚਾ ਨਹੀਂ। ਇਸ ਲਈ ਅੱਠਾ ਨਾਲ ਫੈਸਲਾ ਚੁਣਨ ਹੋਵੇਗਾ। 

ਇਹ ਸਹੇਲੀ ਕਵਿਮੰਤ ਮੈਂ ਕਦੇ ਨਹੀਂ ਕਿਹਾ ਹੋਵੇ। 

ਅਕਾਲਵਾਕਸ ਵੱਲੋਂ 

ਇਸਨੂੰ ਸਹੇਲ ਵਲੋਂ 

ਇਹ ਸ੍ਰੋਤਾਂ ਕੇਂਦਰ 

(ਬੂਟਾਸ਼ਕਾਨਾ)

ਸਾਨੂੰ ਦਿੱਸਨ ਵਿਚਕਾਰ ਦੋਗੇ। 

ਤੋਂ ਇੱਕ ਦੋਗੇ। 

ਤੀਜਾ ਵਾਜ਼ੋਂ ਦੋਗੇ। 

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