REVIEW BOARD ON THE USE OF HUMAN VOLUNTEERS Date 7.8.

CRL

al Investigator MD. AKBAR ALI & DR. AYESHA MOLLA Trainee investigator(if any) _____

tion No 80-034 (P) Supporting Agency(if Non-CRL) NIL

f study Relation between Project status:
Buccal disease and zinc status ( ) New Study
patients ( ) Continuation with change
( ) No change (do not fill out rest of fo

the appropriate answer to each of the following(If Not Applicable write N.

ee of Population:
Ill subjects (Yes)
Non-ill subjects (Yes) No
Minors or persons under guardianship Yes No

s the study involve:
Physical risks to the subjects Yes (No)
Social risks Yes (No)
Psychological risks to subjects Yes (No)
Discomfort to subjects Yes (No)
Invasion of Privacy Yes (No)
Disclosure of information possibly damaging to subject or others Yes (No)

es the study involve:
Use of records (hospital, medical, death, birth or other) (Yes) No
Use of fetal tissue or abortus Yes (No)
Use of organs or body fluids (Yes) No

subjects clearly informed about:
Nature and purposes of study (Yes) No
Procedures to be followed including alternatives used (Yes) No
Physical risks (Yes) No
Sensitive questions (Yes) No
Benefits to be derived (Yes) No
Right to refuse to participate or to withdraw from study (Yes) No
Confidential handling of data 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/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 an overview(all other requirements be submitted with individual studies
   ✓ Protocol (Required)
   ✓ Abstract summary (Required)
   ✓ Statement given or read to subjects nature of study, risks, types of que to be asked, and right to refuse to participate or withdraw (REQUIRED)
   ✓ Informed consent form for subjects
   ___ Informed consent form for parent or guardian NA
   ___ Procedure for maintaining confidenti
   ✓ Questionnaire or interview schedul

*If the final instrument is not comple prior to review, the following inform should be included in the abstract su
1. A description of the areas to be covered in the questionnaire or i view which could be considered ei sensitive or which would constitu invasion of privacy.
2. Examples of the type of specific ions to be asked in the sensitive
3. An indication as to when the ques naire will be presented to the Bo for review.

se to obtain approval of the Review Board on Use of Human Volunteers for an s involving the rights and welfare of subjects before making such change.

Principal Investigator

Trainee

e return 2 copies of entire protocol to Chairman, Review Board on Use of Hum cts.

80-034(P)
recd 18/8/80

SECTION I - RESEARCH PROTOCOL

1. TITLE : Relation between Diarrhoeal Diseases and Zinc status in patients

2. PRINCIPAL INVESTIGATOR : Mr. Akbar Ali & Dr. Ayesha Molla

3. STARTING DATE : As soon as protocol is approved

4. COMPLETION DATE : Three months after starting date

5. TOTAL DIRECT COST : $ 1,642

6. SCIENTIFIC PROGRAMME HEAD

This protocol has been approved by the Working Group

Signature of Scientific Programme Head

Date

7. ABSTRACT SUMMARY

Despite the evidence of zinc deficiency in various diseases including diarrhoea no study has been undertaken to establish the zinc status in diarrhoeal diseases. It has been evident that the conditioning factors of zinc deficiency are related to prevaling syndroms of diarrhoeal diseases. Zinc deficiency was reported in acrodermatitis enteropathica which is characterised by diarrhoea; in diseases with massive intestinal fluid loss, exudation of protein from the intestine, inflammatory bowel and during intravenous alimentation of total parenteral fluid. Bacterial uptake of this element is very high and it is postulated that massive adhesion of barteria in the lumen, inhibiting the gut competes with the host for uptaking

trace metal. The bidirectional movement mucosa to serosa and serosa to mucosa, of this trace metal is sodium and hexose dependent. Zinc is the principal limiting factors in the nutrition of children and neonates. Malnutrition specially in children is associated directly with diarrhoeal diseases. Therefore the hypothesis is that, zinc deficiency may also be associated with diarrhoeal diseases. This research protocol has been undertaken to study the relationship between zinc status and diarrhoeal diseases and thereby gain more knowledge about the important role of this trace element in human health and diseases.

8. R E V I E W S

(a) Ethical Review Committee _____

(b) Research Review Committee _____

(c) Director _____

(d) BMRC _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objective

The objectives of thes study are :

(a) To select and develop an appropriate method for analysis of this metal in the laboratory.

(b) To find out the base line value of zinc status in apparently normal and healthy volunteers from Bangladesh.

(c) To find out the relationship between zinc status and diarrhoeal diseases of different aetiology in matched subjects.

(d) To measure plasma, hair and urinary zinc concentration at different nutritional status and in diarrhoeal diseases of different aetiology in children.

2. Background

In many recent studies the association of zinc deficiency with different diseases have been reported (3, 10, 28-34). The important role of this transition metal in metabolic processess, protein synthesis, cell immunity, cell division, cell growth, biocatalytic activity, microbial toxin production and other biochemical processess have been described by different authors. (1-11). Details of the control mechanisms that regulate zinc absorption in the gut is not clearly known. Some workers reported that zinc absorption occurs through the duodenum and proximal small intestine (10). Zinc is being bound with low molecular weight

ligand (which are protein and assumed to be metalothionine or metalothionine like factor) transported through the intestinal microvillus and into the epithelial cells. In the epithelial cells zinc is transferred to binding sites, on the basolateral plasma membrane, where metal free albumin interacts with the plasma membrane and translocate zinc from the receptor sites (3, 39-41). Being absorbed from the intestine the metal is carried to liver in the portal plasma bound to transferrin. In venous plasma zinc is mostly bound to albumin and to a small extent to transferrin and α-macroglobulins. Liver is the major organ where zinc is metabolised. Copper, high content of calcium, organic phosphate, phytates and fiber in the food inhibit the absorption of zinc from the gut (42-46). Zinc is well absorbed as oxide, carbonate, sulfate or metal (44).

Zinc is present within all body cells; the highest concentrations are found in liver, pancreas, kidney, heart, pituitary, adrenals, prostate and leucocytes (10). The plasma concentration of zinc is 100 $\pm$ 10 μg% (51) in normal adult and serum zinc concentration is 16% higher than that of plasma (52). In Docomenta Geigy the normal value of plasma zinc concentration of adult was given as 10-30 μmol/l i.e. 65-195 μg%. Plasma level of zinc in children

is always higher than the plasma zinc concentration of adult.

Due to deficiency of this element several changes occur which might be related either to nutritional or pathophysiological conditions (10) and fundamental defects may arise in biochemical processess indicating changes in hormones, in enzyme activities and in protein and neuclic acid metabolism (8). In zinc deficient adolencents drawfism and hypogonadism were reported by Prasad (10). An inherited disorder, Acrodermatities enteropathica is resulted from an inborn errors of this trace element metabolism (11). The classical findings of this disease are gastrointestinal dysfunction with diarrhoea, vomiting, severe skin lesion and alopecia. The patients are unable to get the supply of zinc from dietary sources because of gastrointestinal disorder. Oral zinc supplimentation and human breast milk were proved to be of significant therapeutic value in this disorder (12). Zinc deficiency in regional enteritis, steatorrhoea and coeliac sprue - was also reported (13, 14). Solomons et.al. demonstrated that patients secondary to regional enterities and coeliac sprue developed anorexia and hypogeusia probably due to low zinc level (13, 14). These gustatory disfunctions were corrected by the administration of zinc. Osmanski et.al. has also reported that the gustatory disfunctions

are found in zinc deficient rats and also in human subjects (15,16). Prasad also described that the patients suffering from diseases with inflammatory bowel, developed low serum zinc level due to exudation of large amounts of zinc protein complexes into the intestinal lumen (10). Negative zinc balance was also noticed during intravenous alimentation of parenteral solution containing only trace amount of zinc (17, 18, 19). Since zinc absorption occurs through the duodenum and proximal small intestine; adhesion of microorganisms to this part of the elementary cannal, might be the cause of defective zinc absorption through the gut. Micro-organisms inhibiting the gut absorption compete also with the host for uptake of trace metal. Evidence of this concept was demonstrated by Smith et.al. (20) who reported that "visible signs of zinc deficiency were less severe in germ free rats as compared to control animals." At present knowledge about zinc metabolism by the diarrhoea producing organisms is not clearly known. However, studies have been reported to show very high uptake of zinc by Enterotoxigenic E.coli (9,22). Zinc absorption in human intestine is bidirectional and the mechanism is controlled by plasma zinc concentration. The process of transfer of this element from mucosa to serosa and vice versa is dependent upon the presence of Na^+

and glucose (9). Thus in the presence of hyponatraemia or hypoglycemia during diarrhoeal complications zinc metabolism may seriously be hampered. Based on this background it might be hypothesised that due to massive bacterial adhesion to the gut, repeated attack of diarrhoea and prolong exposure to the pathogenic organism precipitation of zinc deficiency might occur in diarrhoeal diseases.

3. Rationale

We are aware of many diseases associated with zinc deficiency, but no specific information is available in zinc deficiency in diarrhoeal diseases though there are some evidences of deficiency of this element in some diarrhoeal diseases, in massive fluid loss from intestine and during intravenous alimentation with parenteral solution. No relationship between etiology of diarrhoeal diseases and subsequent deficiency of this metal was established. Steatorrhoea, protein-calorie malnutrition due to intestinal protein loss, inflamation of bowel, massive intestinal fluid loss, gastrointerites are the most common syndromes in diarrhoeal diseases. There exist an association between diarrhoeal diseases and malnutrition. Zinc is expected to form insoluble complexes with fat and phosphate in alkaline environment (10). Fat malabsorption due to steatorrhoea and regional enterites should result in an increased loss of zinc

in the stool following deficiency of this metal. Recently Lincoln C. Chen et.al. (25) showed that diarrhoea precipitates or exerbates malnutrition through several postulated mechanism and those are reduction of food intake due to child anorexia, malabsorption and direct loss of nutrient from gastrointestinal tract. In zinc deficiency, gustatory disfunction and growth retardation have been evident and it was also shown that zinc is a principal limiting factor in nutrition of the children and neonates. This study undoubtedly contribute to our understanding of the mechanism of anorexia and malnutrition as a consequence of these diseases. The syndrom of diarrhoeal diseases and high uptake rate of this element by microorganisms have been described and from this review it may be postulated that this study would possibly help to establish the relationship of zinc deficiency with these diseases, its etiology and malnutrition subsequent to these diseases.

B. SPECIFIC AIMS

1. To correlate the zinc concentrations in plasma, hair and urine collected from adult volunteers of this centre.
2. To analysis serum, hair or urine from apparently healthy moderately and severely malnourished patients those are coming for treatment in the treatment centre of ICDDR,B.
3. To analyse all data according to sex and age group in different

etiological conditions in matched subjects.

METHODS OF PROCEDURE

1. Specimens will be taken from informed, consenting and apparently healthy volunteer subjects from this Centre. 24 hours urine will be collected under toluene layer and with about 5ml hydrochloric acid. On the same day 2ml blood will be drawn and about 1-2cm long hair from the scalp will be taken by stainless steel scissors (26). Serum and urine zinc will be analysed by atomic absorption spectrophotometer following the method described by J.B. Dawson and B.E.Walker (27)(improved in our laboratory) or any other method which is appropriate in this laboratory. Hair washed with dil. nitric acid is burnt in a muffle furnace and ash is dissolved in 1M Hcl and finally zinc is estimated in atomic absorption spectrophotometer. At least 100 apparently healthy volunteer subjects will be needed for correlating the results of serum, hair and urine.

2. Before entering in the second phase of this study serum zinc will be estimated from those patients who are coming to this centre for diarrhoeal diseases treatment. No separate blood will be drawn for this estimation; 1ml excess blood will be taken with the consent of the patient along with the blood samples for routine clinical estimations which are needed for clinical

diagnosis. Prasad described that a decreased excretion of this element in urine is a valuable indicator of zinc deficiency of man (20). If low urine zinc level in the patients is found with low serum and hair zinc level disregarding sex, age and etiology; in latter part of the study only 24 hour urine will be analysed. Two samples; one on admission and another at the time of discharge will be analysed for each patient. All data will be analysed for: (a) Obtaining relationship among urinary, hair and serum zinc level in disease; disregarding sex, age and etiological conditions. (b) Correlating serum, hair and urinary zinc level. (c) Obtaining relationship of zinc level in different etiological conditions, nutritional status, sex and ages.

D. SIGNIFICANCE

This study will investigate the existence of an association of zinc deficiency and diarrhoeal incidence or zinc deficiency and malnutrition prevalent in diarrhoeal diseases. This study will show the conditioning factors of zinc deficiency in diarrhoeal diseases. Undoubtedly this study will contribute more to our knowledge for understanding the relationship of this trace element with human health and diseases.

E. FACILITIES REQUIRED

1. Office space	:	No additional office space is required
2. Laboratory space and facilities	:	Biochemistry Branch
3. Hospital resources	:	Treatment centre and nurses, one physician will be required to record clinical statement of patients.
4. Animal resources	:	None
5. Major equipment	:	Existing atomic absorption, Spectrophotometer with some new spare parts. One muffle Furnace to be purchased.
6. Other specialised requirement	:	None

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

NAME	POSITION	% OF EFFORT	ANNUAL SALARY	PROJECT REQUIREMENT	US $
bar Ali	Acting Branch Head	25	Tk. 67,490/-	Tk. 4,218/-	281.20
sha Molla		20	Tk.1,15,930/-	Tk. 5,797/-	386.47
ician		20	Tk. 48,080/-	Tk. 2,404/-	160.27
e		20	Tk. 30,390/-	Tk. 1,519/-	101.27
			TOTAL =	Tk.13,938/-	929.21

2. SUPPLIES AND MATERIALS

ITEMS	TOTAL TAKA	US $
Acetyline gas	2,700/-	180.00
Miscellaneous reagents	2,000/-	133.33
Other supplies	2,000/-	133.33
	6,700/-	446.66

3. EQUIPMENT — Not necessary now

4. PATIENT HOSPITALIZATION — Nil

5. OUT PATIENT CARE — Nil

6. TRAVEL AND TRANSPORTATION OF PERSONS

   Local travel — Tk.1,000/- $ 66.67

   International travel

7. TRANSPORTATION OF THINGS

   Import of supplies, 25% of Tk.4,000/- Tk.1,000 $ 66.67

8.	RENT, COMMUNICATIONS AND UTILITIES		
9.	PRINTING AND REPRODUCTION	Tk.2,000/-	$ 133.33
10.	OTHER CONTRACTUAL SERVICE		
11.	CONSTRUCTION, RENOVATION, ALTERATIONS		

BUDGET SUMMARY

1.	PERSONNEL	Tk.13,939/-	$ 929.27
2.	SUPPLIES	Tk. 6,700/-	$ 446.67
3.	LOCAL TRAVEL	Tk. 1,000/-	$ 66.67
4.	TRANSPORTATION OF THINGS Import of supplies 25% of Tk.4,000/-	Tk.1,000/-	$ 66.67
5.	PRINTING AND REPRODUCTION	Tk.2,000/-	$ 133.33
	GRAND TOTAL -	Tk.24,639/-	$ 1,642.61

Total direct cost = Tk.24,639.00

Incremental cost = Tk.10,700.00 $ 713.33

Tk.15.00 = US $ 1.00

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CONSENT FORM

In many of the recent studies it has been reported that zinc deficiency is associated with many diseases and malnutrition. Diarrhoeal diseases and malnutrition is directly related; but no studies have been undertaken to estimate zinc status in diarrhoeal patients. To find out zinc status in diarrhoeal diseases and malnutrition subsequent to these diseases we have undertaken one research protocol. This study protocol will help us to determine the role of this element in diarrhoeal diseases and malnutrition consequent to these diseases and thus contribute more to our knowledge about human health and diseases.

In the first stage of this study blood sample, 24 hours urine and hair will be analysed to establish normal value of this element in apparently healthy people of Bangladesh. (In the second phase of this study samples from those patients coming for treatment in this hospital will be required).

Therefore, if you like to be a volunteer for this study we would request you to donate voluntarily 2cc of blood, 24 hours urine which will be collected by yourself and about 2gm of scalp hair. You have to give those samples only once during study period. (In the case of patients we request you to donate those samples twice during study period). The amount of blood which you will donate is very little and you need not to be worried because it will not be injurious to your health.

Therefore, after fully understanding this information, if you agree to donate those samples voluntarily, please fill up the form and sign it or give your thumb impression.

1. Name _____
2. Age _____
3. Did you suffer from diarrhoeal diseases before? _____
4. If so, how many times _____
5. Did you suffer any other diseases before _____
6. If so, what type of diseases? _____

I have read/been told the information that you have given me and I am willing to help you in this research protocol by donating samples what you need.

_____ _____

Signed / thumb impression Date

সম্মতি পত্র

বর্তমান যুগে বিভিন্ন গবেষণায় দেখা গিয়াছে যে, আমাদের দেহে দস্তার (জিংক) ভাগ কমে যাওয়াতে বিভিন্ন রোগ দেখা দেয়। এই ধাতুর অভাবে অনেকেই অপুষ্টিতে ভুগে থাকে। উদরাময় ও অপুষ্টির মধ্যে সরাসরি সম্পর্ক বিদ্যমান। কিন্তু এপর্যন্ত উদরাময় রোগে এই ধাতুটার পরিমান নির্ণয় করা হয় নাই। উদরাময় রোগে এবং এই রোগ হেতু অপুষ্টির উপর এই ধাতুর প্রভাব নির্ণয় করা যাবে। আমরা আশা করছি এই সমস্যা সমাধান কল্পে এই প্রকল্পটি মানুষের স্বাস্থ্য ও রোগ সম্পর্কে আরও তথ্য পরিবেশন করবে। এই প্রকল্পের প্রয়োজন হবে প্রস্রাব, রক্ত ও মাথার চুল পরীক্ষা করা। (দ্বিতীয় পর্যায়ে এই হাসপাতালে আগত রোগীদের মাথার চুল, প্রস্রাব ও রক্ত বিশ্লেষণ করা হবে।)

তাই আপনি যদি এই গবেষণা প্রকল্পে স্বেচ্ছায় অংশ নিতে চান তবে আপনার মাথার পিছন থেকে ২ গ্রাম মত চুল, ২৪ ঘন্টার প্রস্রাব, যা আপনি নিজেই সংগ্রহ করবেন এবং ২ সি সি-র মত রক্ত দিতে আমরা আপনাকে অনুরোধ করবো। এইগুলো আপনাকে মাত্র একবারই দিতে হবে। (আর আপনি যদি একজন রোগী/রোগীনী হন তবে উপরোক্ত জিনিষগুলো দুইবার দিতে হবে।) অবশ্য দ্বিতীয়বার চুল দেবার প্রয়োজন হবে না। আপনি যে রক্ত দেবেন তার পরিমান নিতান্তই অল্প এবং এতে আপনার শরীরের কোন ক্ষতি হবে না।

যদি আপনি আমাদের অনুরোধ রক্ষা করেন এবং পরীক্ষার জন্য রক্ত, প্রস্রাব এবং মাথার চুল দিতে চান তবে নিম্নের ফরমটি দয়া করে পূর্ণ করুন এবং আপনার স্বাক্ষর অথবা টিপ সহি দিন।

১। নাম----------

২। বয়স----------

৩। আপনি এর পূর্বে কখনও উদরাময় রোগে ভুগেছেন কি? / হাঁ/ / না/

৪। যদি ভুগে থাকেন তবে কতবার----------

৫। অন্য কোন রোগে ভুগে থাকলে তা উল্লেখ করুন।

আমি আপনার গবেষণা সংক্রান্ত পরিবেশিত সকল বিষয়ে অবগত হলাম এবং স্বেচ্ছায় প্রনোদিত হয়ে আপনাদের প্রয়োজনীয় রক্ত, প্রস্রাব ও মাথার চুল দিতে স্বীকার করলাম।

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স্বাক্ষর / টিপ সহি তারিখ