Randomised Control Study on Early Enteral Feeding after Small Gut Anastomosis

By

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DECLARATION

I certify that this dissertation is my own original work and has not been presented for any other award in any other University.

Signed..... Date.....

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DEDICATION

This work is dedicated to: My parents Edward R. Olang and Agnes Olang for their encouragement since my early childhood. My siblings: Beatrice Akinyi, Mourine Adhiambo, Lillian Atieno and Lameck Owino who have been supportive and source of encouragement throughout my career development

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ABBREVIATIONS

DOHS –Duration of hospital stay

EEF –Early enteral feeding

EEN –Early enteral nutrition

GIT –Gastrointestinal tract

GSW – General Surgical Wards

HSD– Hospital Stay Days

KNHERC – Kenyatta National Hospital Ethics and Review Committee

KNH – Kenyatta National Hospital

SPSS – Statistical Package for Social Sciences

UON – University of Nairobi

DEFINITION

Next of kin is either the nearest blood relations according to the law of consanguity or those entitled to take under statutory distribution of intestate's estates…(which) may include a relationship existing by marriage, and embrace persons, who …bear no relation of kinship at all. In this study next of kin for a minor will be the parents or guardians.

ABSTRACT

Background:

Studies show that early enteral feeding after small gut intestinal anastomosis has a better outcome than delayed feeding.The outcome measures are short duration of hospital stay, lower incidence of infection and anastomotic leak. Traditionally enteral feeding has been delayed until the return of bowel sounds or passage of flatus.This practice is not grounded on scientific facts as delayed feeding decreases the deposition of collagen at the anastomotic site, causes mucosal atrophy and negative nitrogen balance .The practice of early enteral feeding (EEF) if adopted will reduce the duration of hospital stay and reduce the overall healthcare costs. Experience in Kenyatta National Hospital (KNH) shows that delayed feeding is preferred after intestinal anastomosis.

Objective: This randomized control study sought to compare the outcome of early enteral feeding versus delayed feeding after small gut anastomosis.

Main outcome measures: The length of hospital stay, infection rate and rate of anastomotic leak.

Study design: Randomized control study.

Setting: Kenyatta National Hospital a tertiary hospital in Kenya.

Study duration: 1st of March to 30th September 2012.

Methods and materials: 66 patients were randomly selected and classified into two groups, group A were fed with liquid diet 6hrs post-operative whereas patients in group B were fed after return of bowel sounds or passage of flatus. The following outcome measures were compared between the study and the control groups: anastomotic leak, wound infection and duration of hospital stay.

Results: The mean length of hospital stay was shorter in the early feeding group (7·3 days, 95% CI 6·9-7·6 days) compared to the delayed feeding group (9·7 days CI 7·6-11·7 days).

This is statistically significant (p=0·02). The anastomotic leak rate was 3% in the delayed feeding group and none in the study group (p=0·314).The wound infection rate was higher in the delayed feeding arm (15%) than in the early feeding arm (6%) p=0·23.

1 INTRODUCTION

1.1 Background

After small intestinal anastomosis the practice has been to delay feeding until bowel sounds resume after which the patient is commenced on graduated feeding. Studies have shown that early enteral feeding has a better outcome in terms of the duration of hospital stay, rate of post-operative infection and rate of anastomotic leak compared to delayed feeding. [1]Early enteral feeding is well tolerated with lower rates of infection and anastomotic leaks leading to short duration of hospital stay and therefore reducing the treatment cost while nil by mouth confers no benefit.[1]Delayed feeding is the preferred practice at KNH after intestinal anastomosis.Studies show that gastric and colonic atony following laparotomy lasts 24-48 hours and that small bowel function recovers function within 4-6hrs .[2]

Surgical injury increases the resting energy and protein expenditure and the nutritional intake fall below the required levels throughout the period of recovery from gastrointestinal tract surgery.[3,4]Early enteral feeding within twenty four hours after laparotomy has been shown to be well tolerated with good absorption. [5]. Delayed feeding has been practiced for fear of physical stress disrupting the anastomosis. The GIT secretions present the anastomotic site with a volume load of approximately 6.8 litres irrespective of delayed or early feeding[6].

1.2 Study Justification

There is evidence that early enteral feeding after small intestinal anastomosis is beneficial to the healing of wounds and anastomotic strength .Early enteral feeding is associated with fewer incidences of anastomotic leak, wound infection and therefore short duration of hospital stay. [1]

There are no studies on EEF after small gut anastomosis locally and in the region. The practice in KNH and the region is to delay feeding until the bowel sounds return. The surgeons practicing delayed feeding base their arguments on the fact that the studies on early feeding are from western populations with different genetic makeup. The aim of this study is to provide local and regional data that can be used to formulate a protocol for early enteral feeding in KNH.

1.3 Study Question

Is there a better outcome with early enteral feeding after small gut anastomosis than delayed feeding in KNH?

1.4 Hypothesis

Null hypothesis: There is no difference in the outcome after small intestinal anastomosis in early and delayed enteral feeding

1.5 Objectives

1.5.1 Broad objective

To determine the outcome of early enteral feedingafter small gutanastomosis

1.5.2 Specific objectives

1) To compare the postoperative length of hospital stay following small gut anastomosis between early and delayed feeding groups.
2) To compare the rate of postoperative infections following small gut anastomosis between the early and delayed feeding groups.
3) To compare the rate of postoperative anastomotic leak following small gut anastomosis between the early and delayed feeding groups.

2 LITERATURE REVIEW

Traditionally enteral feeding after small intestinal anastomosis has been delayed to prevent the development of complications. Various studies suggest that early enteral feeding is beneficial in comparison to delayed feeding.[7, 8]Physiological studies show that post-operative dysmotility predominantly affects the stomach and colon with motility in small intestine being normal within 4 to 8hrs after intestinal surgery[2].Gerald Moss demonstrated presence of peristalsis, absorption and utilization of enteral feeds using barium labelled food and serial x rays, radioactive labelled iodine which was demonstrated in urine within 24hrs after feeding [5]. The physiological studies demonstrating the presence of peristalsis and absorption of food further reinforce the fact that early feeding is well tolerated leading to rapid wound healing and shorter duration of hospital stay[2,5].

Malnutrition is one of the known factors that adversely interfere with wound healing. Studies have shown that up to 40% of inpatients and 50% of surgical patients are malnourished.[9,10] In the perioperative period most surgical patients are in a hyper-catabolic state suggesting that early feeding is necessary to provide the extra calories.[10]In animals starvation reduces collagen deposition on colonic anastomosis site as well as the bursting wall tension leading to poor healing at the anastomotic site.[11]Feeding increases collagen deposition and strength at anastomotic site and reduces mucosal atrophy which adversely interferes with anastomosis healing.[12,13]

Intestinal wound healing is dependent on the precise balance of migration, proliferation, and differentiation of the epithelial cells adjacent to the wounded area[14]. First, epithelial cells surrounding the wound lose their columnar polarity, take on a flattened morphology, and rapidly migrate into the denuded area to restore barrier integrity. This process has been

termed “epithelial restitution.”[15,16,17]. Restitution starts within minutes to hours of injury and is independent of proliferation[15,17]. Proliferation of the mucosal epithelium to increase the pool of enterocytes available to resurface the defect generally begins hours or days after the injury[17]. Finally, maturation and differentiation of epithelial cells is needed to maintain the mucosal barrier function[15].

Early enteral feeding has been shown to preserve gastric secretions and motility, lower intestinal ischemia ,reduce reperfusion injury and maintain mucosal barrier in severe burns patients[18].In critically ill patients on mechanical ventilation early enteral feeding has been shown to reduce mortality[19].Hideya Kamei and colleagues demonstrated a higher level of diamine oxidase enzyme which is integral in the repair of intestinal injury in patients undergoing total gastrectomy and esophagojejunal anastomosis at one week of enteral feeding compared to total parenteral nutrition[20]. Cornelius S Carr et al found that early enteral feeding is safe, well tolerated, prevents an increase in mucosal gut permeability and is associated with a positive nitrogen balance compared to negative nitrogen balance in intravenous fluids group.[21]Schroeder showed that early enteral feeding post-operative is associated with better wound healing.[7]

Studies show that EEF is associated with lower incidence of infection which translates into a short duration of hospital stay. Moore proved that early enteral feeding reduces septic morbidity after trauma, the study group(EEF) had infection rate of 9 % compared to 29% in control group.[22]Beier and Holgerson demonstrated a higher incidence of infection in the delayed feeding group after major abdominal surgery, 46% compared to 6% in the study group[23].Sanjay Marwa in a study on early feeding after intestinal anastomosis found a significant difference in wound infection rate of 4% in study and 20% in the

controlgroup.[27].A study by Braga et al showed that EEF is well tolerated after upper gastrointestinal tract surgery but there was no difference in the duration of hospital stay.[24] Study by Choi et al found that EEF is well tolerated with a short duration of hospital stay 4.2 compared to 6.7 in the control group.[25]

In 2005 SA Fanaie et al found that early feeding six hours after intestinal anastomosis is well tolerated with no difference in the incidence of complications such as anastomotic leak, wound sepsis and wound dehiscence.[26]Sanjay Marwa in 2008 in a comparative study demonstrated that there was significant difference in complication rates among the early fed and the delayed feeding group in patients undergoing elective intestinal anastomosis. The study group had an anastomotic leak rate of 8% compared with 12% in the control group and hospital stay of 5.8 +/-3.9 in the study group and 10.56+/-7.01 days in the control.[27] Di Fronzo et al in a study on EEF after colonic resection and anastomosis had a zero rate of anastomotic leak compared with a leak rate of 3-10% in colorectal surgery[28]. Study by Stewart B T on EEF on colorectal resection showed that the study group had a shorter duration of hospital stay 9 compared to 11.[29]

There is consensus that early feeding is beneficial after intestinal anastomosis. There are differences in the definition of early and enteral. Most studies on early enteral feeding timed the initiation of feeds between 24-72 hours. The definition of enteral feeding ranges from oral (mouth), nasoduodenal or tube jejunostomy[30]. There are very few studies on EEF after small intestinal anastomosis. There is need for more studies with clear definitions on early (6hrs) and enteral (oral) to assess the benefits of early feeding[1]. Early enteral nutrition after upper gastrointestinal surgery leads to faster recovery and short duration of hospital stay of 5.65 in the study arm compared to 12.65 in the delayed feeding arm[31].

3 RESEARCH METHODOLOGY

3.1 Study Population

The study was conducted among all eligible patients scheduled for intestinal anastomosis at Kenyatta National Hospital (KNH) General Surgical Wards, casualty and medical wards who satisfy the inclusion criteria.

3.2 Study Design

Randomized-controlled study.

3.3 Sample Size

Here we set out to test the null hypothesis H_0 that: $\mu_1=\mu_2$ ($mean_1=mean_2$)

$$N = \frac{2\sigma^2\left(Z_{1-\beta} + Z_{1-\frac{\alpha}{2}}\right)^2}{d^2}$$

Where;

N = the sample size required per group

σ = the population standard deviation (σ^2 = the population variance)

1-β = the desired power (β is probability of a type II error {false negative results})

α = the significance level (α is probability of a type II error {false positive results})

d = difference worth detecting between the two groups (e.g. clinically significant difference)

The study sought to test the Null Hypothesis that hospital stay was equal between the two groups i.e. H_0: $\mu_1 = \mu_2$ at α = 0.05 (two-sided) with 90% power and look for a mean difference in hospital stay of 4 days or more. A group standard deviation of 5 days was

assumed (estimated from Marwa *et al*., 2008[27]). Substituting these assumptions in the formula thus:

N =

$$N = \frac{50(3.24)^2}{4^2} = \frac{50(10.4976)}{16}$$

N = 33 participants per group (x2 = total sample size of 66 participants).

An additional six patients will be included to cater for dropouts.

3.4 Variables to evaluate

1. Dependent variables

-Anastomotic leak

- Infection 1) wound sepsis

2) Intra-abdominal abscess

- Length of hospital stay

2. Independent variables

Age and sex

3.5 Participant Recruitment

3.5.1 Inclusion Criteria

1. Patient over 13 years old
2. Patient undergoing small gut anastomosis
3. Patient signs a written consent

3.5.2 Exclusion Criteria

1. Incompetent to provide informed consent
2. Spinal injury.
3. Malignancy.
4. Typhoid perforation.
5. Uncontrolled Diabetes Mellitus.
6. Intra-abdominal sepsis.

3.6 Sampling Method

All eligible patients were recruited into the study. Patients scheduled for elective or emergency small intestinal anastomosis were subjected to randomization based on computer generated numbers. The research randomizer software by Geoffrey C Urbaniak and Scott Plous was used to generate the random numbers. Using the numbers generated the patients were assigned into two groups (study and control).

3.6.1 Patients and methods

The principal investigator and the research assistants who were trained doctors (senior house officers) recruited patients at General Surgical Clinics, casualty and general surgical wards who meet the inclusion criteria. Consent for participation in the study was obtained from the patients after pre-consent counselling. The consent for participation in the study was obtained simultaneously with the consent for surgery.

Operating surgeons were sensitized and recruited into the study before the operations. The sensitization of surgeons had been ongoing since the time of presentation in the department of surgery in early February. Before the study commenced, there were sensitization CMEs

(continual medical education) at the end of the major rounds in all the general surgical wards. Circulars were also used in the general surgical wards, general surgical clinics, casualty and theatres.

Intestinal resection and anastomosis was done as per surgeon's technique (double or single layer of anastomosis). The site of operation and the intra-operative findings were be noted by the operating surgeon. The patients who did not need a resection and anastomosis at laparotomy were disqualified from the study. The disqualified patients were catered for by the additional patients as provided in the sample size calculation.

The patients were randomized into two groups. In the study group, after six hours post-operative (from the time of reversal of anaesthesia) the patients were commenced on oral sips of 5% dextrose for an hour (after removal of nasogastric tube). If this was tolerated, the patient was graduated to 25ml per hour of Fresubin orally. This was continued for 6 hours and if tolerated the patient was encouraged to proceed to liquid diet and subsequently to light diet. Episodes of abdominal distension and vomiting were reported. The patients who were noted to be vomiting (bilious) more than twice or having progressive abdominal distension were stopped from feeding.

In the control group the initiation of feeds commenced upon resumption of bowel sounds either after clinical assessment or passage of stool or flatus. The patient was then started on oral sips, liquid diet, light diet and then normal diet. Liquid diet in both arms was milk, soup or tea. The following were noted; anastomotic leak, infection (wound, intra-abdominal abscess), length of hospital stay.

Wound infection was assessed based on the CDC criteria for surgical site infection, swab for culture and sensitivity in presence of wound discharge.[32]Anastomotic leak was diagnosed based on discharge of intestinal contents from incision or drain site, localized or generalized peritonitis, fever or radiologically using CT scan with water soluble enteric contrast.Intra-abdominal abscess was diagnosed on the basis of an abdominal ultrasound.The indication for surgery, site of anastomosis, signs of infection: temperature, pulse rate and leukocytosis were recorded.

Post-operative follow up was for 30 days. The day the patient was discharged by the attending surgeon was used for calculating the duration of hospital stay. The patients were seen at intervals of two weeks from the date of discharge. Patients who needed reoperation for either intestinal obstruction, intra-abdominal abscess or anastomotic leak with distal obstruction were operated by the primary surgeon or any surgeon handling the ward emergencies at that particular time.

3.7 Data Handling

Data was collected by the principal investigator and research assistant using pre-designed data collection sheets and cleaning was done before analysis. To maintain confidentiality, no name of the study participants was recorded. Data was entered intoMicrosoft Excel ©.Data was then exported to STATA version ten (CollegeStation, Texas, USA) for analysis. The analysis for the various outcomes and comparisons between the two arms of the study was performed using the intent-to-treat (ITT) analysis. Frequency tables and summary statistics were made for the socio-demographic characteristics and the various outcome variables in the two arms of the study. Means, medians and interquartile ranges were calculated and compared between the two arms of the study. Occurrence of adverse outcomes in the

intervention arm of the study was compared with that of the non-intervention arm of the study using the Wilcoxon rank-sum (Mann-Whitney) test. Mean length of hospital stay (in days) was also compared between the two intervention groups using a Student T-test. The results were considered significant if the P-value was less than 0.05.

3.8 Ethical considerations

The study commenced upon approval by the Department of Surgery (UON) and KNH Ethics and Research committee. Informed consent was obtained from each participant prior to enrolment in the study. A pre-consent counselling of the participants was done .The next of kin signed consent on behalf of participants who were unable to do so. Those who declined participation were not denied treatment they deserve because of their decision not toparticipate.

There was no extra cost incurred for participating in the study. Questionnaires and case record forms were locked up in a secure place to ensure confidentiality of patient details. Only the investigator and research assistance personnel had access to the data. Patients' names and other identifying characteristics were not documented and records were encoded to ensure anonymity and confidentiality during data collection and reporting. The primary surgeon was in charge of any complication during the course of the research

4 RESULTS

4.1 Socio-demographic characteristics

A total of 66 patients who underwent small gut anastomosis and met the inclusion criteria were randomly selected and assigned into early and late feeding groups. The recruitment of the study participants ran from 7th of June to September 2012.

The mean age in the early feeding group was 35.1 years and 37years in the delayed feeding group (Table 1). The sex distribution was 57% male and 43% female in the early feeding group while in the delayed feeding group it was 66% male and 33%female (Table 2). There was no significant difference in the age and gender among the two groups. (P=0·52, P=0·447).

Table 1: T-test comparing mean age of participant to feeding

Group	N	Mean Age	95% Confidence Interval	P value
Early feeding	33	35·1	30·7-39·4	P=0·53
Delayed feeding	33	37	39·8-41·2	

Table 2: Chi squared-test comparing gender by treatment group

Gender	Early feeding	Delayed feeding	P value
Male	19(57%)	22 (66%)	P=0·447
Female	14(43%)	11 (33%)	

4.2 Complication rate

The complication rate was higher in the delayed feeding group (21%) than the early feeding group (6%). Seven patients had complications in the early feeding group compared to 2 in the delayed feeding with a p value of 0.073 which is statistically insignificant. Two patients (6%) had wound infection in the early feeding group compared to five (15%) in the delayed feeding group. Two patients (6%) had intra-abdominal abscess in the delayed feeding group and none in the early feeding arm of the study.There was one patient with anastomotic leak and two mortality in the delayed feeding group.

Table 3: A comparison of the complication rates between the two groups

Complication	**Early feeding**	**Delayed feeding**	**P value‡**
Overall complication	2 (6%)	7 (21%)	P=0·073
Wound infection	2 (6%)	5 (15%)	P=0·23
Intra-abdominal abscess	0	2 (6%)	P=0·151
Anastomotic leak	0	1 (3%)	P=0·314
Death	0	2 (6%)	P=0·151

‡p-value generated using a chi-squared test

4.3 Length of hospital stay

The mean length of hospital stay was shorter in the early feeding group 7·3 days while the delayed feeding patients had a mean hospital stay of 9·7 days. The difference was 2·2 days.

Table 4: A comparison of length of hospital stay between the two groups

	Length of hospital stay	95% Confidence interval	p-value
Early feeding	7·3	**7 - 7**·7	p=0·024
Delayed feeding	9·7	7·6 - 11·7	

5 DISCUSSION

After small gut intestinal anastomosis the practice has been to delay feeding until there is clinical evidence of bowel movement. Studies have shown that early enteral feeding has better outcome in terms of shorter duration of hospital stay and lower rates of complication which translates into reduced cost of treatment[1].In spite of the documented evidence the practice of delayed feeding after small gut anastomosis is still the norm rather than the exception in East Africa. Adequate nutrition in the postoperative period is a major goal that is never achieved when feeding is delayed after anastomosis. Early feeding reduces the incidence of infections, improves wound healing and anastomotic strength[22,33]. The results of this study are comparable to the studies done in Western and Asian countries.

After small gut anastomosis the patients in the study group were fed on Fresubin six hours after surgery (reversal of general anaesthesia) while the control group were initiated on feeds after auscultation of bowel sounds or passage of flatus. The ages of the patients ranged from 16 to 66 years. The mean age of the patients in the early feeding group was 35·1 ±2 while the patients in the delayed feeding arm had a mean age of 37±2 years. The difference in age of the patients between the two groups was not statistically significant (P=0·5266).In respect to gender there was no significant difference in the male to female ratio between the two groups p=0·447. In the study group the 19 (57%) were male and the female were 14 (43%). In the control 22 (66%) were male while the female were 11 (33%).

In this study the overall complication rate was higher in the control group 21% than in the study group 6%. The study group had a lower wound infection rate at 6% (2patients) while the control group had a rate of 15% (5 patients) although this difference was not statistically significant p=0·23. This is similar to the study by Sanjay Marwa where the study group had a

wound infection rate of 4% compared to 20% in the control group[27]. The delayed feeding group also had two patients (6%) with intra-abdominal abscess and none in the early feeding group. However this difference was not significant with a p=0·151. This is similar to the study by Lewis where the incidence was higher in the control but not significant[1] p=0·84

The anastomotic leak rate was 3% (one patient) only in the delayed feeding group and none in the study group. This is similar to other studies which found a higher rate of anastomotic leak in the delayed feeding group[1,27]. The improved nutritional intake could have contributed to the lower incidence of anastomotic leak. Delany and co-workers found that early feeding improves wound healing and anastomotic strength[33].Two deaths occurred in the delayed feeding group and none in the early feeding group.

The length of hospital stay is a primary variable in calculating the cost of treatment. The average length of hospital stay was shorter at 7·3 days in the study arm than the control arm at 9·7 days. This was statistically significant with a p=0·024. This is similar to other studies with shorter duration of hospital stay in the study arm p□0·05[25,27]. This is probably due to the lower rate of complications and faster recovery in the study arm leading to quick discharge.

6 CONCLUSION

This study shows that early enteral feeding has a better outcome than delayed feeding in terms of shorter length of hospital stay leading to low treatment cost. The overall complication rate is lower in early feeding compared to delayed feeding although an adequately powered study is necessary to demonstrate a statistically significant difference in the rate of anastomotic leak and infection.

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APPENDIX 1: Case Review Form

Study number:
Demographic information
Age:
Gender:
Date of rectruitment into study:
Intra-operative
Surgery date:
Pathology data form
Operative findings:
Site of anastomosis:

APPENDIX 2: Post-Surgery follow-up

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
purulent discharge from the wound site																														
purulent discharge from drain																														
presence of pain, localized swelling, tenderness and redness/heat																														
microorganisms obtained from aseptically obtained wound culture.																														

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Leakage of intestinal (bilious) fluid from incision or drain site																														
radiological demonstration of a leak with CT scan with water soluble contrast																														

1) Wound condition
2) Anastomotic leak
3) Intra-abdominal abscess yes..... No.....
4) Duration of hospital stay ----------days.....

APPENDIX 3: Criteria for Superficial Incision

A **superficial incisional SSI** must meet one of the following criteria:

Infection occurs within 30 days after the operative procedure andinvolves only skin and subcutaneous tissue of the incisionandpatient has at least one of the following:

a. purulent drainage from the superficial incision.

b. organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.

c. at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision are deliberately opened by surgeon, and are culture-positive or not cultured. A culture-negative finding does not meet this criterion.

d. diagnosis of superficial incisional SSI by the surgeon or attending physician.

NOTE: There are two specific types of superficial incisional SSIs:

1. Superficial Incisional Primary (SIP) – a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CBGB)

2. Superficial Incisional Secondary (SIS) – a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site [leg] incision for CBGB)

APPENDIX 4: CONSENT BY THE PARTICIPATING PATIENT

Study No……. Hospital No……

Purpose of the study

The purpose of this study is to determine the role of early enteral feeding after intestinal anastomosis at Kenyatta National hospital. The information gathered will be used to improve the management of patients undergoing intestinal anastomosis..

Risks and benefits

This study will provide clinicians with essential information on the necessity of early enteral feeding and therefore aid them in improving clinical management of these particular patients. There is no harm or risk anticipated for participating in this study. However, during the study if the researcher identifies a complication on you, he will recommend/ refer you .

Ethical approval

Ethical approval has been obtained from Kenyatta National Hospital/ University of Nairobi

Ethical Review Committee.

Duration and site of study: The study duration is from May 2012 to October 2012 at Kenyatta

National Hospital in the general surgical wards.

The patient has the right to decline to participate in this study. All information availed to the investigator will not be divulged to a third party. The patient will be disqualified from the study in case the intra-operative findings do not warrant a resection and anastomosis.

Contact of KNH/ UON-ERC

Email address: uonknh_erc@uonbi.ac.ke Website: www.uonbi.ac.ke

Address: Kenyatta National Hospital P O BOX 20723 Code 00202

TELEPHONE: 726300-9

Participant signature/ thumb print ……. Phone number …….

DR COLLINS OGUTU OLANG

Bachelor of Medicine and Surgery (MBchB)

CONSENT FORM FOR AN UNDERAGE PATIENT PATIENT

Study No……. Hospital No……

Purpose of the study

The purpose of this study is to determine the role of early enteral feeding after intestinal anastomosis at Kenyatta National hospital. The information gathered will be used to improve the management of patients undergoing intestinal anastomosis..

Risks and benefits

This study will provide clinicians with essential information on the necessity of early enteral feeding and therefore aid them in improving clinical management of these particular patients. There is no harm or risk anticipated for participating in this study. However, during the study if the researcher identifies a complication on the patient, he will recommend/ refer you to the primary surgeon for definitive management.

Ethical approval

Ethical approval has been obtained from Kenyatta National Hospital/ University of Nairobi

Ethical Review Committee

Duration and site of study: The study duration is from May 2012 to October 2012 at Kenyatta

National Hospital in the general surgical wards.

The patient has the right to decline to participate in this study. All information availed to the investigator will not be divulged to a third party. The patient will be disqualified from the study in case the intra-operative findings do not warrant a resection and anastomosis

Contact of KNH/ UON-ERC

Email address: uonknh_erc@uonbi.ac.kewebsite :www.uonbi.ac.ke

Address: Kenyatta National Hospital P O BOX 20723 Code 00202

TELEPHONE: 726300-9

Minor's age:

The undersigned hereby give consent for ……., to be enrolled in this study of early enteral feeding after intestinal anastomosis.

Parent / guardian Name Identity card number

Parent/ guardian signature

Home and work phone number of parents/ guardian

…… ……..

DR.Olang Collins Ogutu– TEL 0729064421

Bachelor of medicine and surgery.

KIBALI CHA RUHUSA

Nambari ya utafiti:……Nambari ya Hospitali:…….

Sababu ya utafiti

Sababu ya utafiti huu ni kuthibitisha manufaaya kula upesi baada ya upasuaji wa matumbo. Utafiti huu utafanyika katika hospitali kuu ya Kenyatta na matokeo yake yatatumiwa kupendekeza njia za kuboresha matibabu kwa wagonjwa ambao wanafanyiwa upasuaji wa matumbo.

Hatari na manufaa

Utafiti huu utaimarisha ujuzi wa madaktari kwa matibabu kwa wagonjwa ambao wanafanyiwa upasuaji wa matumbo. Hatutarajii hatari zozote kwako unaposhiriki kwenye utafiti huu. Iwapo wakati wa utafiti, mtafiti atagundua shida katika matibabu yako, atapendekeza au kukutuma kwa matibabu yanayofaa. Utafiti huu hautakugharimu fedha zaidi.Utafiti huu utafanywa kutoka Mei hadi Oktoba mwaka wa 2012

Uhusika Kwa hiari

Kuhusika kwa utafiti huu ni kwa hiari yako mwenyewe na hauwezi kushurutishwa. Utahudumiwa hata kama utakataa kuhusika kwa huu utafiti. Una uhuru kutamatisha kuhusika wakati wowote bila madhara yoyote île.

Usiri

Habari zozote utakazotoa zitawekwa kwa siri na jina lako halitachapishwa popote.

Idhini ya utafiti

Kabla ya kuanza utafiti huu nitapata ruhusa kutoka kwa kamitii ya utafiti ya kenyata national hospital na chuo kikuu cha nairobi. Ikiwa hautafanyiwa upasuaji wa matumbo basi hautahusika kwenye utafiti.

Barua pepe: uonknh_erc@uonbi.ac.ketovuti :www.uonbi.ac.ke

Sanduku la posta: Kenyatta National Hospital P O BOX 20723 Code 00202

Nambari ya simu: 726300-9

Ninathibitisha yakuwa nimefahamu yale nimeelezwa na mtafiti na nimekubali kwa hiari yangu mwenyewe kuhusika katika utafiti huu.

Sahihi/Kidole cha Gumba (kushoto):

(Mhusika/next of kin) Simu 1 (Mhusika):…… Simu 2 (next of kin):…….

DR.Olang Collins Ogutu 0729064421

Shahada la dawa na upasuaji