Plan Overview

A Data Management Plan created using UCT DMP

Title: Copy of ERATS : Enhanced Recovery After Trauma Surgery, A randomized controlled trial

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Template: UCT Generic Template

Project abstract:

Introduction: Enhanced recovery after surgery (ERAS) protocols have been successfully used in elective gastrointestinal surgery. This has led to improved patient outcomes including reductions in postoperative complications and hospital length of stay. There has been widespread acceptance and implementation thereof. Penetrating abdominal trauma remains a substantial burden of disease, and in the Western Cape, we have seen increasing numbers of these patients. This has resulted in a severe burden on hospital resources. The trauma ward is filled at maximum capacity, with delayed discharges due to poor ambulation; post-operative complications; and delay in return to enteral feeding. There are currently no randomized controlled studies in the trauma literature, which evaluate enhanced recovery after trauma surgery. It is our hypothesis that implementing an “ERATS” protocol, will lead to decreased morbidity, shorter hospital stay with a subsequent decrease in overall costs. Objectives: The primary objective of this study is to evaluate and compare the total length of hospital stay in both treatment groups (ERATS vs non-ERATS). Secondary objectives for this study include assessing overall morbidity, comparative evaluation of early feeding benefits, of earlier removal of nasogastric tubes, intraabdominal drains, and urinary catheters. We aim to evaluate mortality differences between the two groups, perform a comparison between local anaesthetic wound infusion catheters and standard opioid intravenous infusions used post operatively as well as to compare early mobilization techniques with daily goal directed activity versus slow mobilization, and lastly, to a perform a cost analysis between the two groups. Methods: This will be a single - centre, randomized control study (calculated sample size = 42/arm). The intention is to include all hemodynamically stable patients with penetrating abdominal trauma and allocate them to either perioperative care using ERATS protocol versus a control group where they receive standard care.

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Copy of ERATS : Enhanced Recovery After Trauma Surgery, A randomized controlled trial - UCT Outline DMP

1. Project Name

PROJECT NAME - Replicate exactly as in your project, dissertation or thesis proposal.

ERATS : Enhanced Recovery After Trauma Surgery, A randomized controlled trial

2. Lead Principal Investigator(s)/Grant Holder

LEAD/PRINCIPAL INVESTIGATOR(S) OR GRANT HOLDER(S) - Indicate who will take the role of Lead or Principal Investigator (PI) for the project.

Andrew Nicol

3. Data Collection/Generation

COLLECTION OF ORIGINAL DATA/USE OF EXISTING DATA - Indicate whether or not you will produce original data or use existing data (or both), and provide a brief explanation for either case.

- I will produce or collect original data.

This is a randomised controlled trial , with intention to treat and is done prospectively. Therefore original data has to be collected.

EXPECTED DATASET TYPES - Indicate the kind of data will you create or reuse. List briefly the form(s) of data you anticipate you will collect or reuse, along with the estimated size of the total dataset. You may include a short description indicating whether the data will be quantitative, qualitative or mixed methods.

A – DATA CAPTURE SHEET

Folder number	Age	Date of admission	Date of discharge	Time of arrival	Time of discharge	Type of Injury	Injury distribution	Date of surgery	Time of surgery	BP pre op	HR pre op	IVI fluid pre op	Sats pre op

Intra op findings	Total duration of procedure	Fluid intra op	Bloodloss intra op	Removed all tubes intra op : **Catheter: Y/N**	NG tube : Y/N	IVI lines: Y/N	Pre op Antibiotics: Y/N Type	Procedures performed intra op	VTE-calf compressors **Intra op: Y/N**	Recovery time :	HR post op : Day 0	BP Post op Day 0	Sats Post op Day 0

Analgesia pre- op	Analgesia intra op	Analgesia post op Day 0	Analgesia Post op Day 1	Analgesia Post op Day 2	Analgesia Post op Day 3	Analgesia Post op Day 4	Analgesia Post Op Day 5	Analgesia Post op Day 6	Analgesia Post discharge

Urine output: Pre op	Urine output : Intra op	Urine output: Day 0	Urine output : Day 1	Urine output: Day 2	Urine output: Day 3	Urine output: Day 4	Urine output: Day 5	Urine Output: Day 6	Urine Output: Day 7

Pain score pre op	Pain score Post op Day 0 am	Pain score post op Day 0- pm	Pain score Post op Day 1 am	Pain score Post op Day 1 pm	Pain score post op Day 2 am	Pain score Post op Day 2 pm	Pain score post op Day 3 am	Pain score post op Day 3 pm	Pain score post op Day 4 am	Pain score post op Day 4 pm	Pain score post op Day 5 am	Pain score post op Day 5 pm	Pain score post op Day 6 am	Pain score post op Day 6 pm

Complication: Y/N	Diagnosis	Clavien -Dindo classification	Relook: Y/N	Why?	Feeding : Post op	Day 1	Day 2	Day 3	Day 4

ICU admission: Y/N Why	1/52 follow up : Y/N Findings	1/12 follow up: Y/N Findings	Days compliant on ERATS	Baseline Ur/Cr	Discharge Ur/Cr	Baseline Hb	Post operative Hb	Date of discharge	Date of readmission if readmitted

Physio: Post op : Goal achieved Day 0 Y/N Why	Post op : Day 1 : Goal achieved : Y/N Why	Post op Day 2: Goal achieved: Y/N Why	Post op Day 3 Goal achieved Y/N Why	Post op Day 4 Goal achieved Y/N Why	Post op Day 5 Goal achieved Y/N Why	Wound infusion catheter: Y/N	Day 0 :	Day 1	Day 2: Removed Y/N

A total of 84 patients are needed to have statistical significance.
The data collected will be quantitative in nature.

DATA SHARING - Indicate whether or not you are intending to publish your research data, and if so, under what licensing provisions (such as Creative Commons) or access control conditions.

- I do not intend to share my data because of confidentiality issues (details below).

4. Data Storage

DATASET SIZE - Indicate the estimated size of your completed dataset.

- 2-5 TB

DATA VOLUME/STORAGE REQUIREMENTS - If your project anticipates working with large amounts of data, indicate whether or not you will need to access data internal or external data storage facilities. If such storage is not provided by your unit or department, you may need to factor in the cost of purchasing additional storage space.

I currently have enough storage on my internal harddrive on the desktop computer that I am using. I will purchase an external harddrive which will be used exclusively for the research study .

DATA TRANSFER SPEED - If you anticipate using external data storage, consider how important the rate/speed of transfer of large amounts of data is on your research process. If you are not anticipating large data storage, you may skip this question.

- Data transfer speeds are not relevant to my study (skip question).

5. Nominated Data Centre(s)

DATA CENTRES/REPOSITORIES - Regardless of the size of your dataset, it is advisable to curate and/or archive your completed dataset with an established data centre or repository. List relevant data centres/repositories where data will be managed and stored.

- I intend to deposit my data to ZivaHub upon conclusion of my research.

METADATA - Indicate what metadata will accompany your curated dataset, and whether that metadata will be created to a disciplinary best-practices guideline.

Trauma
Enhanced recovery after surgery
Laparotomy
Prospective randomised controlled trial
Penetrating Abdominal trauma

6. Budget

RELEVANT COSTS - Indicate any costs specifically relating to the management and curation of your data, such as digitisation of physical media, data storage or curation charges, and data audits. You do not need to include salary costs for researcher time but may want to note if you intend on hiring a data curator or employing other professional data services.

No costs currently related to management and curation of data .