A Randomized Trial of Supplemental Parenteral Nutrition in

Under and Over Weight Critically Ill Patients:

The TOP UP Trial

Healthy Volunteer Ultrasound Test Manual

Intended Audience: Site Investigators and Trainees

This study is registered at Clinicaltrials.gov.
Identification number **NCT 01206166**

Funded by:

Sponsor: Dr. Daren Heyland

Introduction

The TOP UP Study is a randomized pilot trial of enteral nutrition alone vs. enteral nutrition plus parenteral nutrition in underweight and overweight critically ill patients.

In the context of this pilot study, we propose to evaluate the effect of differential amounts of protein and energy provided to study patients on muscle mass and function. Acquired weakness following prolonged critical illness is an important contributor to ongoing morbidity experienced by survivors of critical illness. Given the emerging evidence that muscle mass and muscle function predict morbidity in surviving patients and that muscle mass at ICU admission may predict length of hospital stay, we can postulate that the beneficial effect of enhanced energy and protein provision is mediated by the preservation (or attenuated deterioration) of muscle mass and increased function in these better fed patients, which would ultimately result in positive outcomes.

In this study, we will evaluate muscle mass in all study patients using bedside ultrasound of the femoral muscle. Before we perform such procedures on the study population, we are proposing to trial the ultrasound protocol in 10 healthy volunteers to allow us to:

- Standardize the training of all Study Investigators performing the US assessment
- Test the feasibility of the procedures
- Determine 'normal' values to which we can compare our measures in the study population
- Determine the inter-rater reliability.

The following pages of this protocol outline the procedures for conducting the ultrasounds in healthy volunteers

Ultrasound Procedure

The Site Investigator/delegate is to take ultrasound measurements on healthy volunteers until a total of 10 volunteers are recruited.

Each ultrasound procedure will be completed first by a trainer and then a second time by a trainee. The trainer and trainee(s) will be determined as per the local site investigator. Record the full name, role and date trained of all staff conducting ultrasounds on the attached log.

Each volunteer will have a total of 4 ultrasound readings done on each leg, two readings per leg by each person doing the ultrasound.

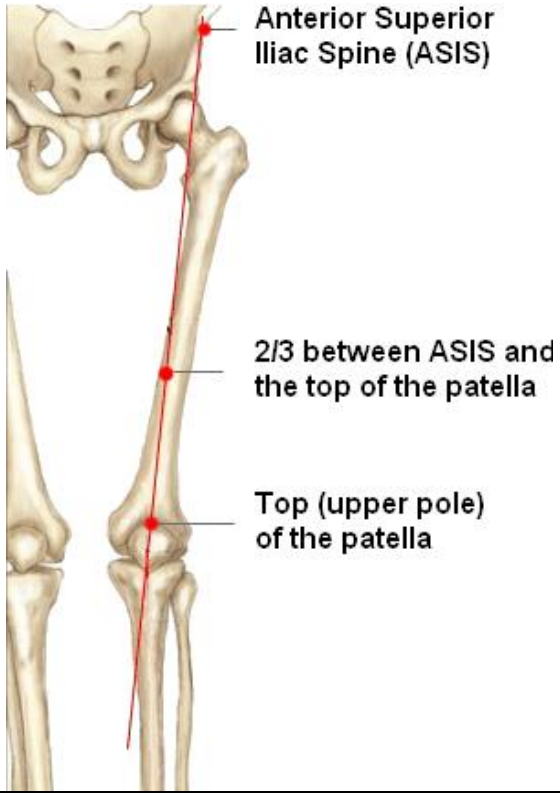
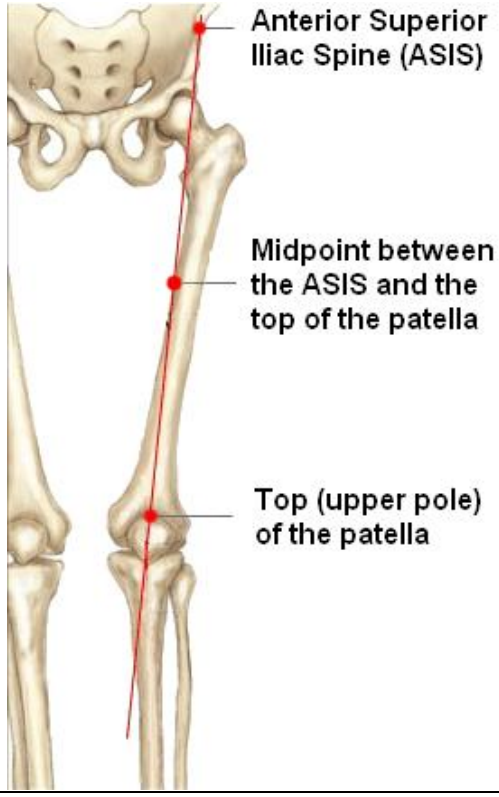
Equipment Required:

1. Portable Ultrasound machine (General Electric Vivid or other portable ultrasound machine) using a high frequency linear transducer.
2. Tape measure

Procedure:

To be performed by two individuals i.e. Trainer and Trainee

1. Lay subject supine with knee extended and relaxed and locate the top of the patella and the anterior superior iliac spine (ASIS).
2. Determine 2 points for measurement of quadriceps femoris muscle

Reading #1	**Reading # 2:**
At the border between the lower third and upper two-thirds between ASIS and upper pole of the patella.  	Athe midpoint between the ASIS and the upper pole of the patella. 

3. Provide generous amount of ultrasound gel to the thigh area that is to be assessed.
4. Hold the ultrasound probe perpendicular to the skin. Use large ultrasound probe (i.e. 5 mHz).
5. Start at maximum depth to identify the femur. ("Depth button") Set the electronic focus depth at the shallowest depth allowable to see the femur for the purposes of measurement.
6. Set frequency (2nd button on the left) at maximum allowable frequency (13 mhz on the GE machine).
7. Compress the probe maximally to measure muscle thickness directly anterior to the shaft of the femur.
8. Take measurements at 2 points as indicated above in # 2
    - Measurement (roller ball or cursor); highlight caliper on screen
    - Mark proximal depth of muscle (press Set)
    - Mark depth @ surface of femur (press Set)
        - Make sure measurement line is perpendicular.
    - Check top left of screen for measurements.
9. Record the measurements in cm as well as the height, weight, age and gender of the volunteer on the provided log (Pg 6-7).
10. Repeat the measurements on the other thigh
11. Avoid measurements on patients who have had recent trauma/operative procedures to leg/hip/knee. Note anything on history relating to the limbs such as previous trauma, neurological disorders, hip or knee replacements.
12. Once test is completed, wipe gel off patient with dry cloth.
13. Wipe down ultrasound machine with Virox; do not use Virox on ultrasound probe. Clean probe with damp cloth only.

Repeat steps 2-13: to be done by trainee (i.e. other Site investigator, Research Coordinator or Dietitian).

Refer to the link provided for the accompanying video.

When done with conducting the ultrasounds on 10 volunteers, please send worksheet to:

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References:

Gruther W et al. Muscle wasting in intensive care patients: Ultrasound observation of the M. Quadriceps Femoris Muscle Layer, J Rehabil Med 2008; 40
Campbell et al. Muscle thickness, measured with ultrasound, may be an indicator of lean tissue wasting in multiple organ failure in the presence of edema, Am J Clin Nutr 1995; 62.

Site Name: _____

Ultrasound Training Log

	Full Name	Role in ICU (ex Investigator, dietician, nurse, research coordinator)	Date trained
Trainee 1			
Trainee 2			
Trainee 3			
Trainee 4			

I hearby attest that I have trained the above persons on ultrasound procedures related to the TOP-UP study.

_____	_____	_____
Full Name	Signature	Date

Site Name: _____

Muscle Function Testing

Ultrasound femoral quadricep	Age	Sex	Height (cm)	Weight (kg)	Date done (YYYY-MM-DD)	Ultrasound 1 (Trainer)		Ultrasound 2 (Trainee)	
						Left Reading (cm)	Right Reading (cm)	Left Reading (cm)	Right Reading (cm)
Volunteer 1						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 2						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 3						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 4						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 5						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint

Site Name: _____

Muscle Function Testing

Ultrasound femoral quadricep	Age	Sex	Height (cm)	Weight (kg)	Date done (YYYY-MM-DD)	Ultrasound 1 (Trainer)		Ultrasound 2 (Trainee)	
						Left Reading (cm)	Right Reading (cm)	Left Reading (cm)	Right Reading (cm)
Volunteer 6						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 7						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 8						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 9						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint
Volunteer 10						2/3rd	2/3rd	2/3rd	2/3rd
						midpoint	midpoint	midpoint	midpoint