



**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](http://Clinicaltrials.gov).  
Identification number **NCT 01206166**

Funded by:



Sponsor: Dr. Daren Heyland



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## Introduction

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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 and intra-rater reliability.

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

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## Ultrasound Procedure

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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, repeated by the trainer (intra-rater reliability) and then an ultrasound be completed on the same volunteer by a trainee (inter-rater reliability). 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 6 ultrasound readings done on each leg, two readings per leg by each person doing the ultrasound followed by repeat readings per leg by trainer.

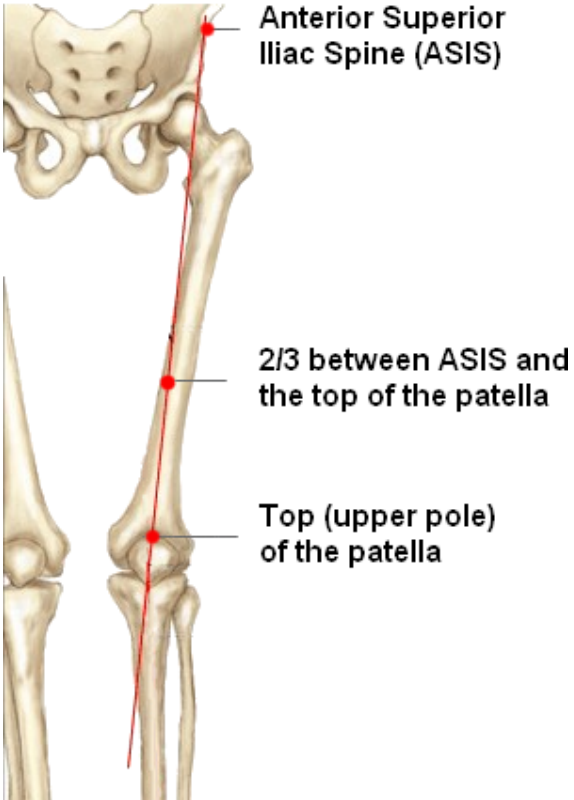
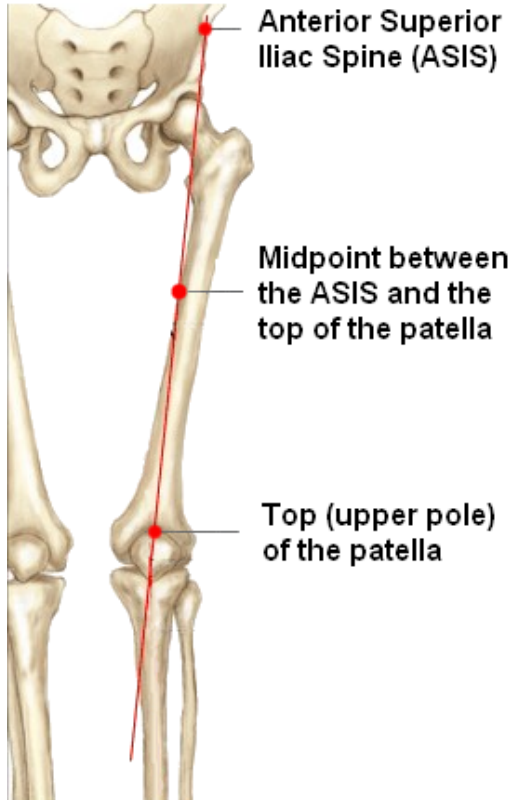
### Equipment Required:

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. Trainer to complete training with Trainee and complete Ultrasound Training Log (page 5)
2. Lay subject supine with knee extended and relaxed and locate the top of the patella and the anterior superior iliac spine (ASIS).
3. Determine 2 points for measurement of quadriceps femoris muscle

Reading #1	Reading # 2:
<p data-bbox="212 1041 789 1125">At the border between the lower third and upper two-thirds between ASIS and upper pole of the patella.</p>  <p data-bbox="472 1129 724 1199"><b>Anterior Superior Iliac Spine (ASIS)</b></p> <p data-bbox="472 1472 789 1541"><b>2/3 between ASIS and the top of the patella</b></p> <p data-bbox="472 1625 716 1694"><b>Top (upper pole) of the patella</b></p>	<p data-bbox="816 1041 1377 1098">At the midpoint between the ASIS and the upper pole of the patella.</p>  <p data-bbox="1089 1129 1341 1199"><b>Anterior Superior Iliac Spine (ASIS)</b></p> <p data-bbox="1089 1367 1341 1472"><b>Midpoint between the ASIS and the top of the patella</b></p> <p data-bbox="1089 1625 1333 1694"><b>Top (upper pole) of the patella</b></p>

4. Provide generous amount of ultrasound gel to the thigh area that is to be assessed.
5. Hold the ultrasound probe perpendicular to the skin. Use large ultrasound probe (i.e. 5 MHz).
6. 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.
7. Set frequency (2<sup>nd</sup> button on the left) at maximum allowable frequency (13 mhz on the GE machine).
8. Compress the probe maximally to measure muscle thickness directly anterior to the shaft of the femur.
9. Take measurements at 2 points as indicated above in # 2
  - o Measurement (roller ball or cursor); highlight caliper on screen
  - o Mark proximal depth of muscle (press Set)
  - o Mark depth @ surface of femur (press Set)
    - Make sure measurement line is perpendicular.
  - o Check top left of screen for measurements.
10. Record the measurements in cm as well as the height, weight, age and gender of the volunteer on the provided Ultrasound Measurements log (Pg 5-6).
11. If conducted by a trainee, record the name of the trainee on the log.
12. Repeat the measurements on the other thigh
13. 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.
14. Once test is completed, wipe gel off patient with dry cloth.
15. 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 repeated by trainer and followed and repeated 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 hereby attest that I have trained the above persons on ultrasound procedures related to the TOP-UP study.

\_\_\_\_\_  
Full Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Site Name: \_\_\_\_\_

## Ultrasound Measurements

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

Site Name: \_\_\_\_\_

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						Left Reading (cm)	Right Reading (cm)	Left Reading (cm)	Right Reading (cm)	Left Reading (cm)	Right Reading (cm)	Trainee Name
6						2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	
						midpoint	midpoint	midpoint	midpoint	midpoint	midpoint	
7						2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	
						midpoint	midpoint	midpoint	midpoint	midpoint	midpoint	
8						2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	
						midpoint	midpoint	midpoint	midpoint	midpoint	midpoint	
9						2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	
						midpoint	midpoint	midpoint	midpoint	midpoint	midpoint	
10						2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	2/3rd	
						midpoint	midpoint	midpoint	midpoint	midpoint	midpoint	