



HRP-591 - Protocol for Human Subject Research

Protocol Title: Weight Change with CAM Boot Use

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Version Date: 30 May 2018

Clinicaltrials.gov Registration #: N/A

1.0 Objectives

1.1 Study Objectives

1. Determine if patients wearing a CAM (Controlled Ankle Movement) walker boot have a change in weight compared to patients who wear a CAM boot and are provided nutritional and upper body exercise (gender appropriate) information at the time the CAM boot is dispensed.
2. Determine, if weight is gained or lost, the average amount gained/lost over the treatment period.

1.2 Primary Study Endpoints

1. Weight gain (or loss) at time patient no longer is required to wear the CAM boot.

1.3 Secondary Study Endpoints

1. Pre- and post-albumin levels (to measure protein and provide nutritional status)

2.0 Background

2.1 Scientific Background and Gaps

There does not appear to be any literature related to this topic. The potential value in completing this study is to provide a better understanding to the health care provider of the necessity to provide information regarding weight maintenance information to the patient when they are placed in a CAM boot for a foot pathology, thereby reducing the risk of weight gain in a CAM boot.

2.2 Previous Data – N/A

2.3 Study Rationale

We hypothesize that participants who are provided nutritional and gender appropriate upper body exercise information, at time CAM boot is prescribed, will maintain their current weight or lose while in the CAM boot. We further hypothesize that participants without nutritional and gender appropriate upper body exercise will gain between 10-15 pounds on average.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

- Participants \geq 18 years of age
- Sex: male or female
- Participants prescribed a CAM boot as standard of care from the principal investigator's practice
- Participants willing to have weight measured at the clinic site at time of enrollment and at final visit
- Participants willing to have blood drawn for Albumin level at beginning and end of study
- Participant is able to provide voluntary, written informed consent
- Participant, in the opinion of the clinical investigator, is able to understand the clinical investigation and is willing to perform all study procedures and follow-up visits.
- Fluent in written and spoken English

3.2 Exclusion Criteria

- Participants $<$ 18 years of age
- Pregnant women
- Cognitive impairment
- Participants with vertigo or other balance issues
- Participants unable to provide informed consent
- Non-English speaking individuals
- Participants who will not be wearing a CAM boot
- Participants unable/unwilling to perform upper body exercises and follow nutrition recommendations

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Participants will be withdrawn from the study for safety reasons including severe adverse reactions, pregnancy, failure of subject to adhere to protocol requirements, or subject consent withdrawal.

3.3.2 Follow-up for withdrawn subjects

If a participant is withdrawn from the study, data collection will be terminated from that time point forward. All prior data collected will be included in the analysis. These participants will not be replaced, but instead more participants may need to be enrolled. These new data will be recorded and analyzed as would any other new enrollee.

4.0 Recruitment Methods

4.1 Identification / Recruitment of subjects

Adult patients presenting to the principal investigator's practice will be evaluated as part of standard of care. Those participants meeting eligibility requirements will be presented with the opportunity to participate in the research study by a member of the research team. These patients would normally be treated at the Penn State Hershey Medical Center and will be receiving the same care as those not enrolled in the study.

4.2 Recruitment materials – N/A

4.3 Eligibility/screening of subjects – N/A

5.0 Consent Process and Documentation

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

Patients presenting to the principal investigator's practice site as part of their initial or routine evaluation will be given the opportunity to participate in the research study. Patients will be given information about the study and asked to participate. If eligible, based on inclusion and exclusion criteria, informed consent will be obtained at the time of the screening visit and the patient will be enrolled in the study.

5.1.1.2 Coercion or Undue Influence during Consent

Study procedures will be fully explained, voluntariness will be emphasized as well as the fact that no care will be denied regardless of the subjects decision. Participants will be given ample time to read and review the consent form on their own. All questions the patient may have will be answered and written consent will be obtained. A member of the research team will assist in the explanation and obtaining of the written consent. A copy of the signed consent will be given to the patient and another copy sent to Medical Records.

5.1.2 Waiver or alteration of the informed consent requirement - N/A

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

A member of the research team will assist in the explanation and obtaining of the written consent. A copy of the signed consent will be given to the patient and another copy sent to Medical Records.

5.2.2 Waiver of Documentation of Consent - N/A

5.3 Consent – Other Considerations - N/A

5.3.1 Non-English Speaking Subjects - N/A

5.3.2 Cognitively Impaired Adults - N/A

5.3.2.1 Capability of Providing Consent - N/A

5.3.2.2 Adults Unable To Consent - N/A

5.3.2.3 Assent - N/A

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission - N/A

5.3.3.1.1 Assent - N/A

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

- Authorization will be obtained and documented as part of the consent process.
- Partial waiver is requested for recruitment purposes only (*Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained*)
- Full waiver is requested for entire research study (*e.g., medical record review studies*)
- Alteration is requested to waive requirement for written documentation of authorization

6.2 Waiver or Alteration of Authorization for the Uses and **Disclosures** of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

N/A: Authorization will be obtained and documented as part of the consent process.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

N/A: Authorization will be obtained and documented as part of the consent process.

6.2.2 Explanation for why the research could not be practicably be conducted without access to and use of PHI

N/A: Authorization will be obtained and documented as part of the consent process.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

N/A: Authorization will be obtained and documented as part of the consent process.

6.3 Waiver or alteration of authorization statements of agreement

N/A: Authorization will be obtained and documented as part of the consent process.

7.0 Study Design and Procedures

7.1 Study Design

This will be a prospective, randomized trial with two groups.

Group 1 (Control) – Patients are prescribed CAM boot as part of their standard of care treatment. No nutritional and exercise information will be provided.

Group 2 (Intervention) – Patients are prescribed CAM boot as part of their standard of care treatment and provided nutritional/exercise information at the time the CAM boot is dispensed.

7.2 Study Procedures

7.2.1 Visit 1 - Enrollment

Patients will be given information about the study and asked to participate. If eligible, based on inclusion and exclusion criteria, informed consent will be obtained at the time of the screening visit and the patient will be enrolled in the study.

After obtaining informed consent, patients will be randomized to one of two groups. A sealed envelope will be drawn containing one of the two treatment groups. This study will not be blinded as patients would easily be able to detect which treatment group they are randomized too.

- **Group 1 (Control)** – Patients are prescribed CAM boot as part of their standard of care treatment. No nutritional and exercise information will be provided.

Patients will be given an Albumin lab test request for blood (8mL) to be drawn at the PSHMC Clinical Laboratories at time of enrollment (+/5 days) and again at their final visit (+/- 5 days). Patients with abnormal lab testing results will be referred to their primary care physician for further evaluation and management.

Patient's height and weight will be measured and recorded using a scale already located in the practice site clinic.

- **Group 2 (Intervention)** – Patients are prescribed CAM boot as part of their standard of care treatment and provided nutritional/exercise information at the time the CAM boot is dispensed.

Patients will be provided upper body physical exercises consisting of seated upper body physical exercises (with or without weights) to include chest press, chest pulls, butterfly wings, front raise, upright row, biceps curls, overhead press and triceps extension exercises (Appendix 1). Patient is instructed to perform these exercises three days per week and each exercise three times per session (or to the best of his/her ability).

Patients will be provided nutritional guidelines (Appendix 2) which is intended as a guide for adults who want to follow a healthful eating pattern.

Patients will also be given a Patient Diary (Appendix 3) to complete their daily meal intake and physical exercises. Use of and return of the diary is optional but encouraged. A dietary scale will also be provided for use throughout the study for weighing food if participants are interested. This is also an optional component of the study. It has been found that use of a patient diary to record food intake and a dietary scale to weigh food helps teach portion control and keeps one from eating more than they planned. They can be useful tools in weight control.

Patients will also be given an Albumin lab test request for blood (8mL) to be drawn at the PSHMC Clinical Laboratories at time of enrollment (+/- 5 days) and again at their final visit (+/- 5 days). Patients with abnormal lab testing results will be referred to their primary care physician for further evaluation and management.

Patient's height and weight will be measured and recorded using a scale already located in the practice site clinic.

7.2.2 Visit 2 – Final Follow-Up Visit

Patients will return to the clinic site for their standard of care visit. At their final visit (when CAM boot use is no longer required), the following will occur:

- **Group 1 (Control):** Patient will be given an Albumin lab test request for blood (8mL) to be drawn at the PSHMC Clinical Laboratories at time of the final study visit. The blood draw

must occur within 5 days of the final visit. Final height and weight will be measured and recorded using a scale located in the practice site clinic.

- Group 2 (Intervention): Final height and weight will be measured and recorded using a scale located in the practice site clinic. Patient will be given an Albumin lab test request for blood (8mL) to be drawn at the PSHMC Clinical Laboratories at time of the final study visit. The blood draw must occur within 5 days of the final visit. Patient will complete the Participant Survey. The dietary scale is to be returned at this visit. Return of the Patient Diary is optional.

	Control	Intervention	
Visit 1 (Enrollment)	Albumin level (bloodwork)	Albumin level (bloodwork)	
	Weight	Weight	
	Height	Height	Patient Diary provided to patient
			Nutritional/Exercise Guidelines provided to patient
			Dietary Scale provided to patient
	Control	Intervention	
Visit 2 (Final Visit)	Albumin level (bloodwork)	Albumin level (bloodwork)	
	Weight	Weight	
	Height	Height	Participant Survey
			Dietary Scale returned
			Patient Diary returned (optional)

7.3 Duration of Participation

Patients will be enrolled in the study from time the CAM boot is dispensed until they no longer need to wear the CAM boot. The patient will be seen a total of two times (enrollment and final follow-up visit).

8.0 Data and Specimen Banking For Future Undetermined Research

N/A

9.0 Statistical Plan

9.1 Sample size determination

Approximately 50 patients will take part in this research study – 25 patients will make up the intervention group (nutritional/exercise information) group and an additional 25 will make up the control group.

We expect the change in weight from baseline to of CAM boot removal + no nutritional information group to increase by 10 lbs. and to remain unchanged (i.e., 0 lbs.) in the CAM boot + nutritional information group. Further, we assume the standard deviation for the change in weight form baseline to time of CAM boot removal will be 12 lbs. Based on these assumptions, a sample size of 25 per group will provide 82% power to detect a difference in the change in weight between the two groups of 10 lbs. using a two-sided test having a significance level if 0.05.

9.2 Statistical methods

Baseline characteristics between the two groups (CAM boot + no nutritional information and CAM boot + nutritional information) will be compared using a chi-square test for categorical variables (e.g., sex) and a two-sample t-test for continuous variables (e.g., the primary of the change in weight from baseline to

CAM boot removal). In the event a continuous outcome is not normally distributed, the nonparametric Wilcoxon Mann Whitney test will be used rather the two-sample t-test.

10.0 Confidentiality, Privacy and Data Management

See the Research Data Plan Review Form

11.0 Data and Safety Monitoring Plan – N/A

12.0 Risks

- Loss of confidentiality – This will be minimized by the appropriate selection of study subjects, access to research records limited to HMC research personnel, compliance with HMC research data and integrity policy, and the use of a study ID code to label all data and specimens .
- Risk of randomization - Participants will be assigned to a treatment program by chance. The treatment received may prove to be less effective or to have more side effects than the other research treatment(s) or other available treatments.
- Risk associated with removing blood by venipuncture is a slight pinch or pin prick when the sterile needle enters the skin. The risks include mild discomfort and/or a black and blue mark at the site of puncture. Less common risks include a small blood clot, infection or bleeding at the puncture site, and on rare occasions fainting during the procedure.
- Risk of injury to participant when conducting upper body exercises. Participants will be provided written instructions on how to perform their upper body exercises at home (using a chair) in order to minimize risk of injury.

13.0 Potential Benefits to Subjects and Others

13.1 Potential Benefits to Subjects

Control Group – none

Intervention Group – minimize weight change

13.2 Potential Benefits to Others

This research may help in the education and treatment of future patients.

14.0 Sharing Results with Subjects – N/A

15.0 Economic Burden to Subjects

15.1 Costs

The albumin level and dietary scale will be provided at no cost to subjects. All other visits are standard of care.

15.2 Compensation for research-related injury

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

16.0 Number of Subjects

See Section 9.

17.0 Resources Available

17.1 Facilities and locations

Penn State Milton S. Hershey Medical Center, Bone & Joint Institute.

17.2 Feasibility of recruiting the required number of subjects

Participants will be identified via their scheduled clinic visit with the research investigator.

17.3 PI Time devoted to conducting the research

Sufficient time will be devoted to conducting the research and reviewing the data.

17.4 Availability of medical or psychological resources – N/A

17.5 Process for informing Study Team

All team members will be given copies of all IRB approved documents – protocol, data collection tools, approval memos, etc. The team communicates regularly to review data and any updates.

18.0 Other Approvals

- Scientific Review Committee

19.0 Subject Stipend (Compensation) and/or Travel Reimbursements

N/A

20.0 Multi-Site Research

20.1 Communication Plans – N/A

20.2 Data Submission and Security Plan – N/A

20.3 Subject Enrollment – N/A

20.4 Reporting of Adverse Events and New Information – N/A

20.5 Audit and Monitoring Plans – N/A

21.0 Adverse Event Reporting

21.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures

21.2 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

22.0 Study Monitoring, Auditing and Inspecting

22.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

23.0 Reference – N/A

24.0 Appendix – N/A