

Adult Informed Consent Example

Title: The influence of consuming a carbohydrate gel on exercise performance and hydration status while exercising at room temperature.

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Introduction

A frequent problem found during exercise for long durations of time (1 hour or more) is maintaining energy levels consistently throughout the exercise bout. Many researchers have found that by consuming carbohydrate supplements during exercise, intensity can be maintained at a consistent level more easily. One such carbohydrate supplement available is the carbohydrate gel.

Carbohydrate gel has a syrup consistency and provides some of the necessary carbohydrates needed during prolonged exercise. Carbohydrates are a fuel used by the body during physical activity, and supply half of the working muscles' energy during a moderate workout and nearly all the energy during an intense workout.

One issue that has risen around carbohydrate gel consumption during exercise is a matter of maintaining hydration status. Recommended estimated amounts of water consumption with carbohydrate gel are available, but these amounts are not consistent or precise.

Purpose

The purpose of this study is to investigate the effects of carbohydrate gel ingestion on exercise performance and hydration status during exercise at room temperature.

Study Procedures

Five visits to the Human Performance Lab will be required to complete the study. The first visit will require 60 minutes, and each subsequent visit will require about three hours of your time. On the first visit you will ride an incremental cycling protocol at room temperature to determine lactic acid threshold. Cycling resistance will increase every three minutes. Exercise will stop when you can no longer maintain peddling cadence. A small fingertip blood sample will be obtained at the end of each interval. Blood samples will be tested for lactic acid. From the generated lactic acid curve, your workload for exercise will be established.

During the next four visits, you will exercise on a cycle ergometer at room temperature. Exercise duration will be 95 minutes in length. During three of these four trials, you will ingest 64 grams of carbohydrate gel with six ounces of water at 20, 50, and 80 minutes of exercise. Exercise workload will be at moderate intensity, one workload below your lactic acid threshold workload. A urine sample will be collected and weight measurements will be recorded before and after exercise. Venous blood samples will be collected pre-, 30 minutes into exercise, 60 minutes into exercise, 90 minutes into exercise, and 30 minutes post exercise. The catheter will be inserted into a forearm vein prior to exercise. Following the final urine collections, blood collections, and weight measurements, you are free to leave.

Risks and Discomforts

You cannot participate as a subject if you have had any medical condition that would endanger your health. This could include heart or pulmonary ailments or diabetes. Risks to you for participating may include: muscle fatigue and soreness from exercise, infection or bruising from blood sampling, an abnormal physiological response to carbohydrate gel ingestion, and lightheadedness. There are no known side effects of ingesting small doses of carbohydrate gel. All blood samples will be handled according to universal safety procedures. You should be aware that your breathing will increase substantially during exercise. Reasonable precautions will be taken to minimize risk to you.

Benefits

Benefits from this study include learning more about carbohydrates as a fuel for physical activity and how carbohydrate gels can impact your exercise performance. You will also learn more about proper water consumption while ingesting carbohydrate gel.

Compensation

You will be paid \$200.00 for completing this study. Additionally, you will receive free lactic acid threshold test (value of \$50.00).

Confidentiality

The confidentiality of the information gathered during your participation in this study will be maintained. Your personal identity will remain confidential. You will not be identified by your name in any published material. All data will be kept in a file cabinet in a locked office.

Voluntary Participation/Withdrawal

Your participation in this study is voluntary. You may decide not to participate or to withdraw your consent to participate in this study at any time, for any reason, without penalty. Your decision whether or not to participate will not affect your current or future relations with St. Cloud State University, the Human Performance Lab, or the researchers.

Payment for participation will occur when you complete the protocol. If you do not complete the protocol, you will still have the benefit of preliminary lactic acid testing results.

The study investigator may stop your participation at any time without your consent for the following reasons: if it appears to be medically harmful to you, if you fail to follow directions for participating in the study, if the study is canceled, or for reasons deemed appropriate by the research coordinator to maintain subject safety and the integrity of the study.

Acceptance to Participate in the carbohydrate gel and hydration study

Your signature indicates that you are at least 18 years of age, you have read the information provided above, and you have consent to participate. You may withdraw from the study at any time without penalty after signing this form.

Subject Name (Printed) _____

Subject Signature _____

Date _____