Impact of Phosphorus Ingestion with Fructose and Glucose on Substrate Utilization in Active Individuals During Moderate Exercise

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Main Information

Primary registry identifying number
LBCTR2020104612

Protocol number
BIO-2019-0257

MOH registration number

Study registered at the country of origin
No

Study registered at the country of origin: Specify
Lebanon

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
07/10/2020

Primary sponsor
University Research Board (URB), American University of Beirut (AUB)

Primary sponsor: Country of origin
Lebanon

Date of registration in primary registry
15/10/2020

Date of registration in national regulatory agency
07/10/2020

Public title
Impact of Phosphorus Ingestion with Fructose and Glucose on Substrate Utilization in Active Individuals During Moderate Exercise

Acronym

Scientific title
Impact of Phosphorus Ingestion with Fructose and Glucose on Substrate Utilization in Active Individuals During Moderate Exercise

Acronym

Brief summary of the study: English

Carbohydrate loading protocols are common among high-level endurance athletes. When the time of exercise exceeds 60 minutes, simple sugars serve as the best exogenous energy suppliers to the exercising muscles.Timing of ingestion and type of carbohydrates are extremely important in these sports. In this study, we would like to assess energy expenditure and substrate oxidation rates following a fructose-glucose load (with or without phosphorus) after a high carbohydrate meal pre-, during, and post-endurance exercise. This will provide insights on effective sports nutrition interventions to increase exercise performance in major endurance-based sports events.

Brief summary of the study: Arabic

تعتبر بروتوكلات الجرعة العالية من الكربوهيدرات شائعة بين الرياضين شديدي التحمل. عندما تزيد مدة التمرين عن الستين دقيقة فإن السكريات البسيطة تعتبر أفضل مزود للطاقة بالنسبة للعضلات التي يتم تمرينها. يعتبر توقيت تناول الجرعة ونوع الكربوهيدرات المستعملة مهم جدا في نوع الرياضة آنفة الذكر. في هذه الدراسة ، نود تقييم معدل الحرق واكسدة الكربوهيدرات والدهون في الجسم البشري بعد استهلاك جرعة من الفركتوز والجلوكوز (مع أو بدون الفوسفور) و تناول وجبة عالية المحتوى من الكربوهيدرات (قبل ، خلال ، وبعد) الرياضة الخاصة بالاشخاص شديدي التحمل. والذي بدوره سوف يوفر رؤية حول فعالية التغذية في تحسين اداء الرياضيين في الاحداث الرياضية الكبرى التي تحتاج قدرة تحمل عالية.

Health conditions/problem studied: Specify

Subjects are healthy and active. No health conditions being studied. Health problems being prevented are cardiovascular event (risk less than 1 in 12,000). This is ensured after a cardiac assessment and approval by a physician from the American University of Beirut Medical Center (AUBMC).

Interventions: Specify

Four protocols will be tested on subjects after assessing their VO2 peak and FATMAX. 3.25 hours after a high carbohydrate meal, participants will ingest fructose, glucose (with or without phosphorus) load. 45 minutes later, they will be asked to cycle at their FATMAX until exhaustion. Energy expenditure and substrate oxidation values will be analyzed for a potential fructose-glucose effect.

Key inclusion and exclusion criteria: Inclusion criteria

Healthy and Active American University of Beirut (AUB) students, Health Insurance Plan (HIP)-covered, non-obese and between the ages of 18 and 35 years.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

35

Key inclusion and exclusion criteria: Exclusion criteria

Previous history of any limitation on physical ability, diabetes, cardiovascular disease (assessed by AUBMC physician), taking supplements or medicine that might affect their metabolic rate, pregnant or breastfeeding, claustrophobic, vegan/allergic to eggs or having unstable bodyweight during the past 6 months.

Type of study

Interventional

Type of intervention

Dietary interventions

Type of intervention: Specify type

N/A

Trial scope

Dose-response

Trial scope: Specify scope

N/A

Study design: Allocation

Single Arm Study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

N/A

Study design: Purpose

Basic science

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

IMP has market authorization: Specify

Name of IMP

Year of authorization

Month of authorization

Type of IMP

Pharmaceutical class

No pharmaceutical product

Therapeutic indication

No therapeutic indication

Therapeutic benefit

Study benefits are mainly on energy expenditure, carbohydrate and fat oxidation and exercise performance

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

20

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

01/11/2020

Date of study closure: Type

Anticipated

Date of study closure: Date

28/10/2021

Recruitment status

Pending

Recruitment status: Specify

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

No IPD sharing statement plan

Additional data URL

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
N/A	N/A

Sources of Monetary or Material Support

Name
University Review Board (URB) at Amercian University of Beirut (AUB)

Secondary Sponsors

Name
N/A

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Elie-Jacques Fares	Department of Nutrition and Food Sciences, Faculty of Agricultural and Food Sciences, American University of Beirut	Lebanon	+9617919 5509	ef08@aub.edu.lb	AUB
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Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
American University of Beirut (AUBMC)	Dr. Afif Moufarrij	Emergency Medicine and Primary Care Sports Medicine	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	24/01/2020	Karine Ismail	irb@aub.edu.lb	Tel:+961-1-738024 or +961-1-350000 ext: 5591

Countries of Recruitment

Name
Lebanon

Health Conditions or Problems Studied

Condition	Code	Keyword
	Carcinoma in situ of other specified sites (D09.7)	N/A

Interventions

Intervention	Description	Keyword
High carbohydrate meal and a load of different glucose, fructose and phosphorus doses	Subjects will come to the lab have a high carbohydrate meal (HCM) calculated according to each participant's body needs: HCM (75% carbohydrates, 15% fat and 10% protein) will be calculated as 30% of each participant's basal metabolic rate (BMR). The meal will contain toast, butter, jam and a shake (egg white powder, starch and sugar) if needed. 3.25 hours later they will have a sugary drink of different composition each time. 4 Visits will be randomized and subjects will be blinded to the type of sugar/phosphorus they are ingesting: High-glucose/Low-fructose (with/without phosphorus), High-fructose/ Low-glucose (with/without phosphorus), before they exercise at FATMAX intensity until exhaustion.	glucose, fructose, phosphorus, carbohydrates

Primary Outcomes

Name	Time Points	Measure
Cardiorespiratory and metabolic responses	Before, during and after exercise	Respiratory quotient (RQ)
Heart rate	Before, during and after exercise	Heart rate (bpm)
Energy expenditure	Before, during and after exercise	Calories by Indirect calorimetry
Fat oxidation grams / calories per minute, percentage energy from fat)	During exercise	FATMAX
Perceived exertion	During exercise	The Borg Scale
Peak oxygen consumption	During exercise	VO2max

Key Secondary Outcomes

Name	Time Points	Measure
N/A	N/A	N/A

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files