# 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 |
| Scientific | 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 |

## 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**