Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

EFFECTS OF COMBINED SAGO–SOY SUPPLEMENTATION ON CYCLING TIME TRIAL PERFORMANCE IN THE HEAT

Protocol summary

Study aim

To investigate the effects of sago (daily used local food containing mostly CHO), soy (daily used local food containing PRO), and iso–caloric sago+soy combined (CHO and PRO combined supplementation) supplementation during a 90–min endurance cycling at 60 % of VO2max on cycling performance, plasma concentrations of glucose, insulin, free fatty acids, and lactate, F2-Isoprostanes, creatine kinase in the heat, as compared to placebo.

Design

The sample size of the current study was calculated by using PS Power and Sample Size Calculation v.2.1.30 (Dupont and Plummer Jr, 2010). In this research, a randomised single–blind, placebo–controlled cross–over trial was applied. The participants for this study were chosen randomly from the Kelantan cycling team. In this study 12 males selected as participants were moderately trained, heat–adapted cyclists. Heat–adaptation in these participants was obtained through existing regular training in a tropical environment (~31 °C; 70 % relative humidity). They have participated in local cycling competitions and were training regularly (three training sessions per week).

Settings and conduct

This study was done in Sports Science Unit, School of Medical Sciences, Health Campus, Universiti Sains Malaysia in Kota Bharu city.

Participants/Inclusion and exclusion criteria

between 15 – 30 years old, Non–smoker, Non–diabetic, Not using dietary supplements, two years of experience in cycling.

Intervention groups

There were four separate trials that were included: Sago-7.5% sago supplement Soy-7.5% soy supplement Sago+Soy-- 6%sago+1.5% soy supplement Placebo Therefore, each participant ingested one of them during each trial.

Main outcome variables

20-km time-trial, Plasma concentrations of glucose, free fatty acids, insulin, lactate, creatine kinase, f2-Isopostance, ratings of perceived exertion, respiratory exchange ratio, and skin and core temperatures.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190906044711N1**
Registration date: **2020-08-03, 1399/05/13**
Registration timing: **retrospective**

Last update: **2020-08-03, 1399/05/13**
Update count: **0**

Registration date

2020-08-03, 1399/05/13

Registrant information

Name

Daniel Tarmast

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2010-09-16, 1389/06/25

Expected recruitment end date

2013-04-09, 1392/01/20

Actual recruitment start date

2010-09-16, 1389/06/25

Actual recruitment end date
2013-04-09, 1392/01/20
Trial completion date
2013-04-09, 1392/01/20

Scientific title
EFFECTS OF COMBINED SAGO–SOY SUPPLEMENTATION ON CYCLING TIME TRIAL PERFORMANCE IN THE HEAT

Public title
Effect of Carbohydrate and Protein Ingestion in Exercise
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Non–smoker Non–diabetic Not using dietary supplements at the time of the study Having, at least, two years of participation in cycling training and competitions
Exclusion criteria:
Age
From **15 years** old to **30 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **15**
Actual sample size reached: **12**
Randomization (investigator's opinion)
Randomized
Randomization description
In this research, a randomised single–blind, placebo–controlled cross–over trial was applied. The study was designed to investigate the effects of iso–caloric sago and soy supplementations through a cycling performance. The protocol was similar to an actual race in which each cyclist consumed a type supplementation in one of the experimental trials with a one week washout period between the crossover phases. There were four experimental trials in this design where the participants were randomly assigned to consume either Sago, Soy, Sago+Soy, or Placebo before and during the experimental trials. Random number tables have been used for each supplement to assign the treatments among the participants.
Blinding (investigator's opinion)
Single blinded
Blinding description
In the current study, all of the cyclists were blinded, and they were not informed about the type of supplementation as their taste was similar. In addition, the laboratory technicians were also not informed about the type of supplementation. The only person who was aware of the type of supplements was the Ph.D. candidate acting as the investigator.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ministry of Science, Technology and Innovation Malaysia
Street address
Putrajaya, Malaysia
City
Kuala Lumpur
Postal code
62000
Approval date
2007-11-12, 1386/08/21
Ethics committee reference number
USM/0000814

Health conditions studied

1

Description of health condition studied
To investigate the effects of sago (daily used local food containing mostly CHO), soy (daily used local food containing PRO), and iso–caloric sago+soy combined (CHO and PRO combined supplementation) supplementation during a 90–min endurance cycling at 60 % of VO2max on cycling performance in the heat
ICD-10 code
Y93.79
ICD-10 code description
Activity, other specified sports and athletics

Primary outcomes

1

Description
The 20–km time trial performance in the heat,
Timepoint
At 20 min intervals during cycling at 60% VO2max, participants consumed either SA, SO, SS, or a PL.
Method of measurement
This test was performed by using the electronically braked ergometer (Excalibur Sport, Lode, Groningen, The Netherlands). Participants were requested to perform the 20–km time trial on another bike (One Series Aluminium, Trek Road Bikes, USA). This bike was supported by a trainer (CycleOps Power JetFluid Pro Trainer, Wisconsin, USA). Meanwhile, they were free to control the speed of the cycling via a digital cyclometer (Cateye Strada Wireless, CC–RD300W, Japan). During the experimental

trials, heart rate was measured by a heart rate monitor (S710, Polar Electro, Finland). A heart rate monitor sensor (Sport Tester, PE 3000, Polar Electro, Finland) was fitted on the chest wall of the participants' body to transmit the data to the heart rate monitor.

2

Description

Blood glucose

Timepoint

The blood sampling (8 mL) were collected after at -30 min, 0 min, 30 min, 60 min, 90 min, and after time trial performance.

Method of measurement

Enzymatic oxidation method was applied to analyse the plasma glucose concentration within 60 minutes by spectrophotometer (Spekol 1200, Germany).

3

Description

Free Fatty Acid

Timepoint

The blood sampling (8 mL) were collected after at -30 min, 0 min, 30 min, 60 min, 90 min, and after time trial performance.

Method of measurement

Acyl–CoA synthetase–Acyl–CoA oxidase method (ACS–ACOD) was used to analyse the plasma Free Fatty Acid concentration by spectrophotometer (Spekol 1200, Germany) at 550 nm.

4

Description

Insulin

Timepoint

The blood sampling (8 mL) were collected after at -30 min, 0 min, 30 min, 60 min, 90 min, and after time trial performance.

Method of measurement

The Roche Cobas insulin method (ROCHE Elecsys 2010, Roche Diagnostics, USA) was applied in this research to measure the insulin concentration which employs a biotinylated monoclonal insulin–specific antibody and a monoclonal insulin–specific antibody.

5

Description

Lactate

Timepoint

The blood sampling (8 mL) were collected after at -30 min, 0 min, 30 min, 60 min, 90 min, and after time trial performance.

Method of measurement

The analysis of lactate was done by using commercial reagent kit (Cobas, USA)$_9$ by the auto-chemistry analyser (Roche Hitachi 912 Analyser, USA).

6

Description

Creatine Kinase

Timepoint

The blood sampling (8 mL) was collected after at -30 min, immediately after the time trial, and 24 hours after time trial performance.

Method of measurement

N–acetyl–L–cysteine method (NAC) was used to measure the CK concentration by an auto analyser (Abbott Aeroset C–8000, USA) using a commercial kit (7D63–21, Creatine Kinase Reagent Kit).

7

Description

F2–Isoprostanes

Timepoint

The blood sampling (8 mL) was collected after at -30 min, immediately after the time trial, and 24 hours after time trial performance.

Method of measurement

An enzyme immunoassay (EIA) was used to detect the presence of the F2-Isoprostanes (8-iso Prostaglandin F2α) in plasma by considering enzyme–linked immunosorbent assay (ELISA) method by a photometric microplate reader (Molecular Devices; Versamax Tunable Micro Plate Reader, USA).

8

Description

Ratings of Perceived Exertion

Timepoint

Every 15 min of the cycling.

Method of measurement

Throughout the experimental trials, ratings of perceived exertion were obtained from the participants by the Borg's Scale (Borg, 1998) which is a rating scale ranging among 6 to 20 to show the Ratings of Perceived Exertion.

9

Description

Respiratory Exchange Ratio

Timepoint

Every 15 min of the cycling.

Method of measurement

The metabolic measurement system (SensorMedics™ VMax Spectra 29, USA) was used to determine respiratory exchange ratio.

10

Description

Core and Mean Skin Temperatures

Timepoint

Every 15 min of the cycling.

Method of measurement

Libra Medical ET 300R temperature monitor (Libra Medical Corporation, USA) was used for continuous measurement of core temperature of the participants. To

calculate the mean skin temperature, a formula (Ramanathan, 1964) was used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sago-These ingredients were sago flour (75 gr in 1 liter) that obtained from Sim Company Sdn. Bhd. Penang (Ghosh et al., 2010), and it was mixed with 5 mL of non–caloric chocolate flavour (Star Brand, FFM Marketing Sdn. Bhd., Selangor, Malaysia) in 1000 mL of each drink. The sago supplement was iso–caloric, and the energy value of them was estimated ~ 300 kcal. All participants were supplemented 5 times at 0, 20, 40, 60, and 80 minutes in the cycling.

Category

Treatment - Drugs

2

Description

Intervention group: Soy-These ingredients were soy flour (75 gr in 1 liter) that obtained from Sim Company Sdn. Bhd. Penang (Ghosh et al., 2010), and it was mixed with 5 mL of non–caloric chocolate flavour (Star Brand, FFM Marketing Sdn. Bhd., Selangor, Malaysia) in 1000 mL of each drink. The soy supplement was iso–caloric, and the energy value of them was estimated ~ 300 kcal. All participants were supplemented 5 times at 0, 20, 40, 60, and 80 minutes in the cycling.

Category

Treatment - Drugs

3

Description

Intervention group: Sago+Soy-The preparation of this supplement was similar to the sago or soy ingestions, but 60 g of sago flour and 15 g of soy flour were used (Ghosh et al., 2010). This supplement was mixed with 5 mL of non–caloric chocolate flavour (Star Brand, FFM Marketing Sdn. Bhd., Selangor, Malaysia) in 1000 mL of each drink. The Sago+Soy supplement was iso–caloric, and the energy value of them was estimated ~ 300 kcal. All participants were supplemented 5 times at 0, 20, 40, 60, and 80 minutes in the cycling.

Category

Treatment - Drugs

4

Description

Intervention group: Placebo-The non–caloric chocolate flavour was added to the boiled 1000 mL of distilled water. This solution was consumed as non–caloric supplementation of a placebo trial.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Sports Science Unit, School of Medical Sciences, Universiti Sains Malaysia (USM)

Full name of responsible person
Daniel Tarmast

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name
e-Science Fund

Grant code / Reference number
USM/0000814

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Sports Science Unit, School of Medical Sciences, Universiti Sains Malaysia

Proportion provided by this source
100

Public or private sector

Public

Domestic or foreign origin
Foreign

Category of foreign source of funding
Sponsor: country of origin

Country of origin
MY

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Daniel Tarmast

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The data of the current study belongs to the Universiti Sains Malaysia, and these data were collected for the Ministry of Science, Technology and Innovation Malaysia.

When the data will become available and for how long

By permission.

To whom data/document is available

Only available for people working in academic institutions.

Under which criteria data/document could be used

Additionally, for any athletic purposes.

From where data/document is obtainable

Sports Science Unit, School of Medical Sciences, Universiti Sains Malaysia (USM).

What processes are involved for a request to access data/document

Approximately, one month after a request the data will be discussed to either send or not. Then, 1 or 2 additional months will be available for the person who has requested.

Comments