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Drinking soft drinks fast or slow, which one is better?

Submission date
21/05/2021

Recruitment status
No longer recruiting

Registration date
01/06/2021

Overall study status
Completed

Last Edited
08/07/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Drinking sweetened beverages is associated with an increased risk of heart disease and type 2 diabetes. The aim of this study is to determine if the speed of drinking the sweetened beverage alters the effects of fructose (fruit sugar).

Who can participate?
Healthy adult volunteers who are free of any chronic illness and do not routinely use any medication

What does the study involve?
Participants are randomly allocated to one of two groups. After overnight fasting, participants in group 1 drink 500 ml of apple juice over an hour by drinking 125 ml every 15 minutes, while subjects in group 2 drink 500 ml of apple juice over 5 minutes. Blood samples are collected at 0, 15, 30, 60, and 120 minutes after ingestion to be tested for levels of sugar and other factors.

What are the possible benefits and risks of participating?
Participation is on a voluntary basis and does not provide individual benefits. Risks include the risks of having blood drawn, which are mainly temporary pain due to needle stick and bruising.

Where is the study run from?
Koc University Hospital (Turkey)

When is the study starting and how long is it expected to run for?
June 2020 to December 2020

Who is funding the study?
Koc University Research Center for Translational Medicine (KUTTAM) (Turkey)

Who is the main contact?
Prof. Dr. Mehmet Kanbay
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title

The effects of speed of ingestion of a sugary beverage on the acute metabolic response to fructose

Acronym
SPEFRU

Study objectives
It is hypothesized that the metabolic effects of fructose in sugary beverages might be modulated by the speed of ingestion in addition to the overall amount.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2020, Koc University Committee on Human Research (Rumelifeneri Mahallesi, Rumelifeneri Yolu, 34450, Sariyer, Istanbul, Turkey; +90 (0)212 338 11 76; chr@ku.edu.tr), ref: 2020.275.IRB1.098

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Determination of the metabolic response to fructose after fast versus slow ingestion of 100% fruit juice

Interventions
Thirty healthy, nonobese participants without any systemic disease and receiving no medications and alcohol are included in this study. Each subject is given a total of 500 ml of 100% pure, commercially available apple juice to consume during the intervention. The participants are randomly allocated to either group 1 or group 2. The study used 100% apple juice as the fructose source since it has a higher fructose-to-glucose ratio and has no antioxidant effect. Each participant drinks the same apple juice. The participants in group 1 are instructed to drink 125 ml every 15 min under direct supervision four times until a total of 500 ml is consumed. The participants in group 2 are instructed to drink 500 ml of apple juice within 5 min under direct supervision. No other eating or drinking is allowed during the 2 h study period for both groups. The subjects do not perform any physical activity during the study period. Blood samples are collected for laboratory analysis at baseline and 15, 30, 60, and 120 min after apple juice consumption initiation

Intervention Type
Other

Primary outcome(s)
1. Serum glucose measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice

2. Insulin measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice
3. FGF-21 measured using sandwich enzyme-linked immunosorbent assay (ELISA) using commercial kits (Cloud-Clone Corp., Wuhan, China) at baseline, and 15, 30, 60, and 120 min after drinking apple juice. Sera is separated in aliquots and is frozen rapidly at -80 °C for the measurements.
4. Copeptin measured using sandwich enzyme-linked immunosorbent assay (ELISA) using commercial kits (Cloud-Clone Corp., Wuhan, China) at baseline, and 15, 30, 60, and 120 min after drinking apple juice. Sera is separated in aliquots and is frozen rapidly at -80 °C for the measurements.
5. Osmolarity measured using the freezing-point Osmometer K-7400S (Knauer, Berlin, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice
6. Sodium measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice
7. BUN measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice
8. Lactic acid measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice
9. Uric acid measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice
10. Phosphate measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) at baseline, and 15, 30, 60, and 120 min after drinking apple juice

Key secondary outcome(s))
HOMA-IR measured using the following formula: HOMA-IR = (plasma glucose × plasma insulin /405), where glucose is in mass units (mg/dL), measured using a Roche Cobas 6000 analyzer (Roche, Mannheim, Germany) and calculated for baseline, and 15, 30, 60, and 120 min after drinking apple juice

Completion date
01/12/2020

Eligibility

Key inclusion criteria
1. Healthy, nonobese participants
2. No systemic diseases
3. Not taking medications or alcohol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Obesity
2. Any systemic disease
3. Receiving any medications routinely
4. Significant alcohol use

Date of first enrolment
01/09/2020

Date of final enrolment
01/12/2020

Locations

Countries of recruitment
Türkiye

Study participating centre
Koc University Hospital
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Sponsor information

Organisation
Koc University Research Center for Translational Medicine (KUTTAM)

Funder(s)

Funder type
University/education

Funder Name
Koc University Research Center for Translational Medicine (KUTTAM), funded by The Presidency of Turkey, Presidency of Strategy and Budget

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dr Mehmet Kanbay (mkanbay@ku.edu.tr).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/06/2021	08/06/2021	Yes	No
Participant information sheet			08/07/2021	No	Yes