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

Submission date	Recruitment status No longer recruiting	Prospectively registered	
21/05/2021		[] Protocol	
Registration date	Overall study status	[] Statistical analysis plan	
01/06/2021	Completed	[X] Results	
Last Edited 08/07/2021	Condition category Nutritional, Metabolic, Endocrine	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 mkanbay@ku.edu.tr

Contact information

Type(s) Scientific

Contact name Prof Mehmet Kanbay

ORCID ID https://orcid.org/0000-0002-1297-0675

Contact details Koc University Hospital Topkapi Davutpasa Cd. No:4 Istanbul Türkiye 34010 +90 (0)5423536986 mkanbay@ku.edu.tr

Type(s)

Public

Contact name Dr Lale Ertuglu

ORCID ID https://orcid.org/0000-0002-6318-4199

Contact details

Koc University Hospital Topkapi Davutpasa Cd. No:4 Istanbul Türkiye 34010 +90 (0)5369334311 lertuglu14@ku.edu.tr

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Other

Participant information sheet See additional files

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 measure

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

Secondary outcome measures

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

Overall study start date

10/06/2020

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

Age group

Adult

Sex

Both

Target number of participants 30

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

Topkapı, Koç Üniversitesi Hastanesi Davutpaşa Cd. No:4 Istanbul Türkiye 34010

Sponsor information

Organisation Koc University Research Center for Translational Medicine (KUTTAM)

Sponsor details

Topkapi, Davutpasa Cd. No. 4 Istanbul Türkiye 3401 +90 (0)850 250 8 250 ctunit@ku.edu.tr

Sponsor type University/education

Website https://kuttam.ku.edu.tr/

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

Publication and dissemination plan

Planned publication in Nutrients

Intention to publish date 20/06/2021

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

Results article

Detai	ls Date created	Date added	Peer reviewed?	Patient-facing?
	02/06/2021	08/06/2021	Yes	No

08/07/2021 No

Yes