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Effect of oat-containing biscuit on sugar metabolism

Submission date	Recruitment status	[ ] Prospectively registered
20/09/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/11/2023	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/11/2023	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Oat is believed to provide health benefits. This study will examine how the ingestion of biscuits, containing beta-glycan fibers from oats, affects blood sugar by using a standard finger prick test for blood sugar.

Who can participate?
Healthy female volunteers aged between 20 and 40 years old

What does the study involve?
After oral intake of a beta-glycan-containing biscuit participants will be subjected to an oral glucose tolerance test (OGTT). The test involves the collection of capillary blood at regular intervals for 2 hours. After around one week the OGTT will be repeated, this time without intake of a biscuit. Testing will take a total of around 3 hours each time.

What are the possible benefits and risks of participating?
The participants will contribute to advanced research on metabolic regulation and this can be of future help for persons affected by diabetes. The risk from participation is negligible. The oat-containing biscuit is a normal nutrient and is not expected to cause any harm. The testing procedure involves blood sampling which can cause minor discomfort.

Where is the study run from?
The study will be run in Singapore by Temasek Polytechnic’s Glycemic Index Research Unit

When is the study starting and how long is it expected to run for?
December 2020 to December 2023

Who is funding the study?
Enterprise Singapore (Singapore)

Who is the main contact?
gunnar.norstedt@ki.se (Sweden)

Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of beta glycan-containing biscuits on the Oral Glucose Tolerance Test

Study objectives
Beta glycan may change oral glucose tolerance tests by reducing peak values

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/08/2021, Temasek Polytechnic Institutional Review Board (School of Applied Science, Temasek Polytechnic, East Wing Blck 1A, 21 Tampines Ave 1, Tampines , 529765, Singapore; +65 6780-5322; irb@tp.edu.eg), ref: IRB210702

Study design
Non-randomized cross-over study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Pharmaceutical testing facility

Study type(s)
Prevention, Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Sugar metabolism in healthy volunteers

Interventions
Healthy volunteers will be asked to come fasted to the clinic. Then they will be subjected to a routine oral glucose tolerance test (OGTT) using fingerprick blood sampling with and without prior ingestion of a biscuit containing oat beta-glucan.

On day 0, One biscuit containing beta glycan derived from oats will given before the OGTT. A week later the same individual will be subjected to another OGTT this time without prior ingestion of the biscuit.

Intervention Type
Supplement

Primary outcome measure
Capillary blood sugar measured using the oral glucose tolerance test on days 0 and 7

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/12/2020

Completion date
01/12/2023

Eligibility

Key inclusion criteria
1. Females
2. Not pregnant
3. No medical condition
4. Age between 20-40 years old

Participant type(s)
Healthy volunteer, Learner/student

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
Any known medical condition

Date of first enrolment
01/06/2023

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Singapore

Study participating centre
National University Hospital Singapore
5 Lower Kent Ridge rd
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Sponsor information

Organisation
Temasec Polytechnic

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Government

Funder Name
Enterprise Singapore

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/11/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The type of data stored is the result of oral glucose tolerance tests, age and gender. Data files can only be requested by contacting our public contact Micael Györei, micael@gloobe.se. The timing for availability is from December 12, 2023. Participant consent is required and was obtained
Anonymised data will be stored.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.2	26/01/2021	06/11/2023	No	Yes