ISRCTN49467722 https://doi.org/10.1186/ISRCTN49467722

Do breads made from different grains increase blood sugar similarly? A study in healthy volunteers

Submission date
22/12/2025

Recruitment status
No longer recruiting

Registration date
30/12/2025

Overall study status
Completed

Last Edited
30/12/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at registration.

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Prof Jutta Dierkes

ORCID ID
https://orcid.org/0000-0003-0663-877X

Contact details
Department of Clinical Medicine, Centre for Nutrition, Jonas Lies vei 86
Bergen
Norway
5021
+4795448279
jutta.dierkes@uib.no

Additional identifiers

Study information

Scientific Title
Glycemic index of whole grain breads produced from different cereals: a randomized cross-over study in healthy volunteers

Study objectives
To investigate whether the blood glucose response is different after ingestion of whole grain bread prepared from oat, barley or rye compared to bread prepared from wheat.
To investigate the glycemic index of whole grain breads prepared from different cereals.
To investigate whether the insulin increase is different after ingestion of whole grain bread prepared from oat, barley, rye or wheat.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/06/2025, Regional Committees for Medical and Health Research, Northern Norway (MH-bygget, 12th floor, Breivika, UiT Norges arktiske universitet (Tromsø), Tromsø, 9037, Norway; +47 776 46 140; rek-nord@asp.uit.no), ref: 900039

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Crossover

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Postprandial glycemia in healthy volunteers

Interventions
Healthy adult volunteers fulfilling the inclusion criteria will be invited to the main study. The order of testing the different breads and the glucose will be in random order for each volunteer, with a washout period of at least 48 h between two tests. The volunteers will arrive at 8 am at the Research Unit, then a fasting blood sample is taken, and one of the breads is ingested in random order, within 10 minutes and in a blinded fashion (as this is an investigation with real food, difficulties in the blinding cannot be excluded, but will be minimized as far as possible). Further blood samples are taken at 15, 30, 45, 60, 90 and 120 minutes. Randomisation is performed using EasyTrial block randomisation.

Breads: The breads will be produced at Nofima in a pilot-scale bakery (registered with Mattilsynet for commercial food production). Each bread will be portioned at Nofima to have 50 g available carbohydrate and then shipped frozen to Bergen and thawed before the test day. Glucose solution (50g) will be used for the calculation of the glycemic index.

Blood sample taking: The participants will receive an intravenous catheter at each study day for sampling of venous blood for the measurement of glucose and insulin.
Capillary glucose will be measured with the Hemocue Glucose 201 system, a point-of-care device recommended for monitoring of blood glucose. The Hemocue Glucose 201 system is based on the modified glucose dehydrogenase principle with photometric measurement of glucose.

Intervention Type
Other

Primary outcome(s)
1. Incremental area under the curve between 0 and 120 min of capillary blood glucose measured using HemoCue Hb201+ analysers (mmol/L/min) at baseline, and after 15, 30, 45, 60, 90 and 120 minutes

Key secondary outcome(s)
1. Incremental area under the curve between 0 and 120 minutes of serum insulin measured using Siemens Immulite 2000 XPi chemiluminescence immunoassay (mU/L/min) at baseline, and after 15, 30, 45, 60, 90 and 120 minutes

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. Healthy volunteers without known or unknown diabetes mellitus, excluded by a fasting glucose measurement and a measurement of HbA1c
2. Age range 18-60 years

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment

0

Key exclusion criteria
1. Pregnancy
2. Breastfeeding
3. Reduced ability to give informed consent
4. Alcohol or other substance abuse
5. Use of drugs that may interfere with glucose concentrations
6. Chronic diseases like cardiovascular diseases, cancer, or chronic obstructive lung disease are a reason for exclusion when they occurred during the last three years and require continued treatment
7. Diabetes mellitus

Date of first enrolment
01/10/2025

Date of final enrolment
30/05/2026

Locations

Countries of recruitment
Norway

Sponsor information

Organisation
University of Bergen

ROR
https://ror.org/03zga2b32

Funder(s)

Funder type

Funder Name
Nofima

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location
Sweden

Funder Name
Universitetet i Bergen

Alternative Name(s)
University of Bergen, University of Bergen, Norway, Universitas Bergensis, UiB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			23/12/2025	No	No