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Carbohydrate intake and risk of developing gestational diabetes

Submission date
19/10/2017

Recruitment status
No longer recruiting

Registration date
23/10/2017

Overall study status
Completed

Last Edited
10/07/2018

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Gestational diabetes (GDM) is high blood sugar (glucose) that develops during pregnancy and usually disappears after giving birth. It is one of the most common pregnancy complications and increases the risk of adverse pregnancy and health outcomes for both mothers and their offspring. Carbohydrate restriction and evenly spreading carbohydrate intake throughout the day helps women with GDM to control their blood glucose levels. Carbohydrate intake and the glycaemic load (quality and quantity of carbohydrate) of the pre-pregnancy diet may also influence the risk of developing GDM according to one US study. However, whether this is also the case for other populations is not known. The aim of this study is to examine the associations between glycaemic index, glycaemic load, and carbohydrate content of the pre-pregnancy diet and the risk of developing GDM in an Australian population.

Who can participate?
Women born in 1973–78 in the young cohort of the Australian Longitudinal Study on Women's Health (ALSWH)

What does the study involve?
Data is collected from the ALSWH study, including dietary intake data collected in 2003 and 2009 and information on pregnancies that occurred between 2003 and 2015, to assess the association between different aspects of carbohydrate intake and the development of GDM.

What are the possible benefits and risks of participating?
There are no benefits or risks of participation.

Where is the study run from?
University of Queensland (Australia)

When is the study starting and how long is it expected to run for?
January 2017 to November 2017

Who is funding the study?
Department of Health (Australia)

Who is the main contact?
Moniek Looman

Study website
https://www.alswh.org.au

Contact information

Type(s)
Scientific

Contact name
Ms Moniek Looman

Contact details
PO Box 17
Wageningen
Netherlands
6700 AA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
A650

Study information

Scientific Title
Pre-pregnancy dietary carbohydrate intake and risk of developing gestational diabetes in an Australian population

Study objectives
Carbohydrate quantity and quality affect postprandial glucose response, glucose metabolism and risk of type 2 diabetes. However, research investigating pre-pregnancy carbohydrate quantity and quality in relation to gestational diabetes (GDM) risk is limited.

Ethics approval required
Old ethics approval format

Ethics approval(s)

University of Newcastle Human Research Ethics Committee, approval no's. H-076-0795 and H-2012-0256
University of Queensland Medical Research Ethics Committee, approval no's. 2004000224 and 2012000950

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
This study is an analysis using data of the ongoing prospective population-based prospective cohort study: the Australian Longitudinal Study on Women's Health (ALSWH). ALSWH investigates the role of demographic, social, physical, psychological, and behavioral factors in women's health. Full details on study design, recruitment, methods and responses have been published.

In 1996 approximately 15,000 women born in 1973–78 (18–23 years) were recruited for participation in the young cohort of the ALSWH study. Women were randomly selected from Australia's nationalized health-care system, Medicare, with intentional oversampling in rural and remote areas. Self-administered questionnaires assessing demographic, social, lifestyle and reproductive factors were sent to participants every 3-4 years. The most recent survey was completed in 2015.

For the current study, dietary intake data (collected in 2003 when women were 25-30 years old and 2009 when women were 31-36 years old) was used as well as information on pregnancies of the women that occurred between 2003 and 2015. From the dietary intake data, total carbohydrate intake, total sugar intake, total fiber intake, glycemic index, glycemic load and intake of carbohydrate rich food groups was calculated. The association between different aspects of carbohydrate intake and development of gestational diabetes was assessed using multi-variable generalized equation estimates. Women who were pregnant at time of dietary intake assessment were excluded for analyses to be able to investigate pre-pregnancy dietary intake.

Intervention Type
Other

Primary outcome measure
Development of gestational diabetes, assessed using questionnaire data about pregnancies that occurred between 2003 and 2015

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2017

Completion date
01/11/2017

Eligibility

Key inclusion criteria
Participants from the young cohort from the ALSWH study with information on dietary intake and pregnancies between 2003 and 2015

Participant type(s)
All

Age group
Adult

Sex
Female

Target number of participants
3500

Key exclusion criteria
1. No report of a live birth between 2003 and 2015
2. Missing data on diet
3. Missing data on gestational diabetes diagnosis
4. Implausible energy intake (ratio of reported energy intake and predicted energy requirement <0.56 or >1.44)
5. History of type 1 or type 2 diabetes mellitus prior to GDM diagnosis
6. History of GDM prior to baseline

Date of first enrolment
01/03/2017

Date of final enrolment
01/04/2017

Locations

Countries of recruitment
Australia

Study participating centre
University of Queensland
Brisbane
Australia
4006

Sponsor information

Organisation
University of Queensland

Sponsor details
266 Herston Rd
Brisbane
Australia
Herston QLD 4006

Sponsor type
University/education

ROR
https://ror.org/00rqy9422

Funder(s)

Funder type
Government

Funder Name
Department of Health, Australian Government

Alternative Name(s)
Australian Government Department of Health and Aged Care, Dept of Health & Aged Care, Department of Health, Australian Government Department of Health, The Department of Health, Australian Dept of Health & Aged Care, healthgovau, Department of Health and Aged

Care · Aged Care, Australian Department of Health and Aged Care, Department of Health, Australian Government, Department of Health and Aged Care, The Department of Health and Aged Care, DHAC, DoHAC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan
The results of this study will be published in a peer-reviewed scientific journal

Intention to publish date
01/01/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed for this study will be available upon request. A request can be made by submitting an EOI form via the ALSWH website (https://www.alswh.org.au/how-to-access-the-data/alswh-data). The specific datasets and analysis of this registration belong to EOI A650 and can be requested after approval of the ALSWH scientific committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No