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Efficiency of following Mediterranean diet recommendations in the real world in the incidence of gestational diabetes mellitus

Submission date
11/10/2016

Recruitment status
No longer recruiting

Registration date
26/10/2016

Overall study status
Completed

Last Edited
13/07/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Gestational Diabetes Mellitus (GDM) is a heath condition that occurs during pregnancy where the body becomes unable to produce enough insulin – a hormone that helps to control the amount of sugar in the blood – to meet the extra needs during pregnancy. The condition usually resolves itself after the mother has given birth. There is growing interest in GDM due to an increase in the number of women being diagnosed with the condition. It can have harmful consequences for both mother and baby. The mother, for example, can develop gestational hypertension (high blood pressure) and pre-eclampsia (a condition that causes high blood pressure and can lead to some serious pregnancy complications if left untreated). GDM can also the baby to grow larger than usual (macrosomia) , which can result in a difficult delivery and the need for induced labour or caesarean section, low blood sugar levels (hypoglycemia), high insulin levels (hyperinsulinemia) shoulder dystocia (a condition where it is difficult to deliver the shoulders of the baby after the head has already been delivered), and an increased risk of obesity (being very overweight) and type 2 diabetes later in life. A significant number of women who have had GDM will develop type 2 diabetes later in life and may be at increased risk of cardiovascular (for example heart) disease. Researchers have looked at the effect of the Mediterranean diet on the prevention of GDM, providing free olive oil and nuts to patients (study record ISRCTN84389045). There is some preliminary data showing a decrease in the number of women developing GDM after eating a Mediterranean diet(with recommendations of reducing fat intake to < 30% and saturated fat < 10% of total intake). This study is looking at whether an universal nutritional recommendation based on the Mediterranean diet in the real clinical setting (for example, a hospital) , with the usual obstetric and endocrinological follow-up will be as effective as when tested as part of a clinical study.

Who can participate?
Pregnant women over the age of 18 with high blood glucose levels.

What does the study involve?
All participants are given advise on diet to be followed during their pregnancy.
Recommendations include having fresh vegetables at both lunch and dinner every day and up to

3 pieces of fresh fruit every day. They are also advised to use extra olive oil for cooking and salad dressings, to have nuts every day and to eat 3 portions of semi-skimmed dairy products. They are also told to eat wholegrain cereals and to avoid biscuits, pastries and cakes. They are encouraged to partake of moderate physical activity (for example, to climb four floors of steps four times a day) every day. They are assessed during their usual visits to the Obstetrics department. During their first visit, they are asked to fill in a nutritional questionnaire and give blood samples as well as sit a medical interview. They then receive nutritional recommendations during their second visit and are tested throughout their pregnancy for GDM and to check whether they are following the dietary advice.

What are the possible benefits and risks of participating?
All the participants will gain nutritional education beneficial for the development of their pregnancy. There are no side effects.

Where is the study run from?
Hospital Clínico San Carlos, Madrid (Spain)

When is the study starting and how long is it expected to run for?
February 2016 to June 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Nuria García de la Torre Lobo

Contact information

Type(s)
Scientific

Contact name
Dr Nuria García de la Torre Lobo

ORCID ID
http://orcid.org/0000-0003-3546-9231

Contact details
Servicio de Endocrinología y Nutrición.
Hospital Clínico San Carlos. C/Profesor Martín Lagos s/n.
Madrid
Spain
28040

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficiency of a dietary intervention based on the Mediterranean diet in the clinical setting in the incidence of gestational diabetes mellitus

Study objectives
The efficacy of a nutritional intervention in the clinical setting based on the mediterranean diet is not inferior to the results obtained from a clinical trial (ISRCTN84389045) in the incidence of gestational diabetes mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CEIC Hospital Clínico San Carlos, 08/11/2016, ref: 16/442-E

Study design
Unicentric prospective and interventional

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Gestational Diabetes Mellitus

Interventions
A nutritional intervention based on the Mediterranean diet will be given to all pregnant women attending the study hospital in the first gestational visit (gestational weeks 8 to 12).

All participants will have the usual follow-up visits in the Obstetrics department, and also in the Endocrinology department in case gestational diabetes is diagnosed.

Visit 0: between 8-12 gestational weeks: Consent signature, medical interview, blood sample, and nutritional questionnaire.
Visit 1: one week later: inclusion criteria compliance, blood sample, and nutritional recommendations.
Visit 2: Between 24-28 gestational weeks; oral glucose tolerance test with 75 g of glucose for identification of gestational diabetes with the IADPSG criteria, nutritional questionnaire and blood and urine sample.
Visits 3-4 (and 4', if needed): Gestational weeks 28 to 38 if they are diagnosed with gestational diabetes for the usual follow up in the Endocrinology department.
Visit 5: 38 gestational week: nutritional questionnaire, blood and urine sample.
Visit 6: 12 weeks postpartum: clinical evaluation, nutritional questionnaire and blood sample.

The intervention will include these main recommendations:
1. To have fresh vegetables at lunch and dinner daily (any type of vegetables)
2. To have fresh fruit for dessert at lunch and dinner daily (maximum 3 portions a day, avoid juices)
3. To use extra virgin olive oil daily for cooking and dressings
4. To have nuts daily (as snacks and for salads)
5. To have 3 portions of semi skimmed dairies daily
6. To have wholegrain cereals instead of whites. To avoid biscuits, pastries, and cakes
7. To perform moderate physical activity (to climb four floors of steps four times daily)

Intervention Type
Behavioural

Primary outcome measure
Incidence of gestational diabetes mellitus at 24-28 gestational weeks. The diagnosis of gestational diabetes mellitus will be established with a 75 g oral glucose tolerance test according to the criteria o IADPSG 2009 and WHO 2013.

Secondary outcome measures
Current secondary outcome measures as of 04/12/2018:
Participants were enrolled at 8-12 gestational weeks (GWs) (visit 0) and were followed-up at GWs 12-14 (visit 1), 24-28 (visit 2), 34-36 (visit 3-4) and delivery (visit 5), as well as at 12 weeks post partum (visit 6):
1. The diagnosis of GDM was established with a 75 g oral glucose tolerance test according to the criteria of IADPSG 2009 and WHO 2013 in visit 2.
2. Pregestational body weight (BW) was self-referred and registered at Visit 1. BW in each visit (1,2, 3 and 4) was measured without shoes and with lightweight clothes. Weight gain was evaluated at 24-28 and 36-38 GW (in relation to BW at Visit 1)
3. Blood pressure was measured with an adequate armlet when the participants had been seated for 10 minutes
4. Need of insulin therapy was registered from endocrinology clinical records after GDM diagnosis at visit 2 (Visits 2, 3 and 4)
5. Pregnancy-induced hypertension (≥140mmHg systolic blood pressure/90 mmHg diastolic blood pressure after 20 GW)
6. Preeclampsia (≥140mmHg systolic/90 mmHg diastolic with proteinuria ≥300 mg in 24-h after 20 GW; albuminuria (proteinuria≥ 300 mg in 24-h with systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg)
7. UTIs (number of events requiring antibiotic treatment) recorded at each visit
8. Type of delivery (vaginal, instrumental or caesarean section) and perineal trauma (any degree

of spontaneous tears and episiotomy) recorded from obstetric clinical records
9. Gestational age at birth, prematurity (<37 GW), birth weight (g), height (cm) and percentiles, LGA, SGA according to national charts, and NICU admissions were registered from clinical records.

Previous secondary outcome measures:
Percentage of women with a weight gain at the last gestational visit (weeks 37-40)

Overall study start date
01/02/2016

Completion date
01/06/2020

Eligibility

Key inclusion criteria
Pregnant women older than 18 with fasting glucose levels < 92 mg/dl in the first gestational visit (gestational week 8 to 12).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
873

Total final enrolment
1066

Key exclusion criteria
1. Pregnant women with fasting glucose levels >92 mg/dl in the first gestational visit (gestational week 8 to 12)
2. Intolerance/allergy to nuts or olive oil, multiple pregnancy, and any disease or medical treatment that can have an effect on the intervention. Women with specific nutritional treatments

Date of first enrolment
01/11/2016

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Clínico San Carlos
calle Profesor Martín Lagos s/n
Madrid
Spain
28040

Sponsor information

Organisation
The Health Research Institute of San Carlos (Instituto de Investigación Sanitaria San Carlos)

Sponsor details
San Carlos Hospital. (Hospital Clínico San Carlos)
c/Profesor Martín Lagos s/n
Madrid
Spain
28040

Sponsor type
Research organisation

ROR
https://ror.org/014v12a39

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The trialists hope to have results published from phase 1 before the end of 2019. Results from phase 2 will be published in 2021.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
Please request access to participant level data by emailing nurialobo@hotmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		26/10/2016	23/11/2016	No	Yes
Results article	results	28/05/2019	15/01/2020	Yes	No