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Incidence of gestational diabetes mellitus (GDM) and the Mediterranean diet

Submission date	Recruitment status	[X] Prospectively registered
31/05/2016	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/06/2016	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/06/2019	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gestational diabetes is a type of diabetes that only affects pregnant women. Insulin is a hormone that controls the amount of glucose (sugar) in the blood. Like other forms of diabetes, gestational diabetes can result in too much sugar (glucose) in the blood; during pregnancy, some woman can develop a higher than usual concentration of glucose in the blood which insulin is not able to control properly. Gestational diabetes usually appears in the third trimester (after 28 weeks) and disappears after the baby is born. However, it does markedly increase a woman's changes of developing type 2 diabetes in the future and also cardiovascular disease (such as heart disease and stroke). It is therefore very important to find ways of reducing the number of women who develop gestational diabetes. The Mediterranean diet has been proven to reduce cardiovascular risk and type 2 diabetes. The aim of this study is to test whether different components of the Mediterranean diet (one high in olive oil or nuts) have a different effect on the likelihood of a pregnant woman developing gestational diabetes.

Who can participate?
Pregnant women aged at least 18 with normal blood glucose levels.

What does the study involve?
Participants are randomly allocated o one of two groups. Those in group 1 are asked to eat a diet including at least 1/2l of olive oil a week. Those in group 2 are asked to eat a diet containing at least 75g of nuts a week. The olive oil and the nuts are provided by the researchers. All participants are also asked to increase the amount of fresh fruit they eat, eat whole grain cereal and to avoid foods such as biscuits, sweets, pastries, jams and precooked meals. All participants are also asked to do some regular, moderate exercise. They are all followed up throughout their pregnancy to see whether they stick to the diet. They are asked to fill out dietary questionnaires and provide blood and urine sample for analyses.

What are the possible benefits and risks of participating?
Benefits for participants include nutritional advice and regular checks to see whether they stick to dietary recommendations. There are no risks involved in participating in the study.

Where is the study run from?
Clinico San Carlos Hospital (Spain)

When is the study starting and how long is it expected to run for?
May 2016 to December 2017

Who is funding the study?
Pistachos del Sol SL (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
14355

Study information

Scientific Title
Incidence of gestational diabetes mellitus (GDM) with different components of the Mediterranean diet

Study objectives
Different components of the mediterranean diet (such as olive oil or nuts) affects the incidence of gestational diabetes mellitus (GDM)

Ethics approval required
Old ethics approval format

Ethics approval(s)
CEIC Hospital Clínico San Carlos, 15/07/2016, ref: 7.1/16

Study design
Single centre clinic-based prospective randomized interventional study

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Women will be assigned to the "olive oil" group with recommendations of consuming at least 1 /2l of olive oil weekly or the "nuts" group where 75 g of nuts will be provided weekly. All women will be advised to increase consumption of fresh fruits instead of juices, whole grain cereals instead of white cereals, and to avoid biscuits, sweets, pastries, jams and precooked meals. This intervention has an approximate 35-40% amount of fat, of which more than 50% is mono and polyunsaturate, 40-45% of carbohydrates with a low glycemic load and 20% of proteins. All women will be advised to exercise moderately on regular basis.

Randomisation: a randomisation matrix will be built. Patients will be stratified and matched by age, BMI, number of births, and ethnicity in a 1: 1 fashion.

Follow-up: The following visits have been programmed:
1. Visit 0: between 8-12 gestational weeks: Consent signature, medical records, blood sample and dietary questionnaire
2. Visit 1: one week later: Inclusion criteria, randomisation, blood sample and dietary intervention.
3. Visit 2: between 16-18 gestational weeks: dietary questionnaire, adherence to recommendations, medical follow-up
4. Visit 3: between 24-28 gestational weeks: after a minimum of 12 weeks intervention patients will have a 75 g oral glucose load and gestational DM will be identified according to the IADPSG criteria, dietary questionnaire and blood a urine sample
5. Visits 4 and 5: between 28-38 gestational weeks: for gestational DM follow-up in case patients have been diagnosed
6. Visit 6: 38 gestational week: adherence to recommendations, dietary questionnaire, blood and urine sample
7. Visit 7: 3 months postpartum: Clinical evaluation, dietary questionnaire and blood sample

Intervention Type
Supplement

Primary outcome(s)
Incidence of gestational DM in each group diagnosed with a 75 g oral glucose load by IADPSG criteria at 24-28 gestational weeks.

Key secondary outcome(s))
1. Incidence of pre-eclampsia during pregnancy, as assessed using a blood pressure measurement
2. Number of instrumental delivery and caesarean sections at birth, as assessed using obstetric medical records
3. Number of small for gestational age new-borns, macrosomic new-borns, assessed using birth weight
4. Number of admissions to the paediatric intensive care unit at birth

Added 29/07/2016:
5. Weight gain is assessed by calculating BMI from height and weight at the 8-12 weeks gestational visit and the 38 gestational week visit

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Pregnant women at least 18 years old
2. Normal fasting blood glucose values in the first gestational assessment

Added 29/07/2016:
3. BMI >25 and <35

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Women with fasting blood glucose >92 mg/dl in the first gestational assessment
2. Nuts or olive oil intolerance
3. Multiple pregnancy and any medical condition, treatment or diet intervention that the medical team consider to influence the effects of the study intervention.

Date of first enrolment
01/09/2016

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
Spain

Study participating centre
Clinico San Carlos Hospital (Hospital Clínico San Carlos)
Calle Profesor Martín Lagos s/n
Madrid
Spain
28040

Sponsor information

Organisation
Biomedical Research Institute (IdISSC) Foundation for Biomedical Research, Clinico San Carlos Hospital (Instituto de Investigación Biomédica (IdISSC) Fundación para la Investigación Biomédica, Hospital Clínico San Carlos)

ROR
https://ror.org/03mfyme49

Funder(s)

Funder type
Industry

Funder Name
Pistachos del Sol SL (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes