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Diabetes mellitus and abnormal glucose tolerance development after gestational diabetes

Submission date	Recruitment status	[_] Prospectively registered
11/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
Diabetes mellitus and abnormal glucose tolerance development after gestational diabetes: a 3-year, prospective, randomised, clinic-based, interventional study with parallel groups

Acronym
DIATAGEST

Study objectives
It is well established that gestational diabetes confers a substantial risk of development diabetes and glucose intolerance. Accumulated incidence rates of diabetes mellitus in these women vary among different studies, being up to 50% in 5 years, with lower incidence in Caucasian populations. In addition, these women present higher rates of risk factors for cardiovascular disease and metabolic syndrome, including smoking status, hypertension, dyslipidaemia, central obesity, insulin resistance and abnormalities in vascular endothelium and microalbuminuria. We assumed that women had normal glucose values (less than 100 mg/dl) between 6 - 12 weeks after delivery and progressed to diabetes after oral glucose tolerance test (OGTT) at 2% per year and greater than 10% per year for impaired fasting glucose (IFG) or impaired glucose tolerance (IGT). Lifestyle intervention has been associated with a reduction in diabetes and glucose intolerant progression, but this remains to be proven in a real world situation.

The study hypothesis is to assess the reduction in the conversion to abnormal glucose tolerance (IFG and IGT), and type 2 diabetes after a lifestyle and exercise supervised-based programme, compared to standard treatment, in women attended in Area 7, Madrid who were diagnosed with gestational diabetes (GDM) by Couston and Carpenter criteria and normal glucose tolerance between 6 and 12 weeks after delivery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Carlos Hospital Ethics Committee, 19/01/2007

Study design
Single-centre clinic-based prospective randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

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

Health condition(s) or problem(s) studied
Gestational diabetes/diabetes mellitus prevention

Interventions
Eligible women with normal fasting plasma glucose values between 6 and 12 weeks after delivery were randomly assigned to receive:
1. Standard treatment: 1 hour education session and follow up by family physicians at primary care level
2. A lifestyle, exercise-supervised intervention programme
Adjustments were made for age, body mass index, use of insulin during gestation and ethnic origin.

Lifestyle exercise-supervised programme was performed during 8 weeks in the Rehabilitation Unit at the St Carlos University Hospital between 3 and 6 months after delivery and reinforced during 1 hour sessions at the end of the supervised period, 3 and 6 months later.

The supervised physical activity programme consisted in a combined supervised aerobic and resistance training of 50 - 60 minutes per session, four days a week: two days at the hospital and other two days at home, for eight weeks. The physical activity included a proper warm-up and cool-down period, 20 minutes of cycling at moderate intensity and 20 minutes resistance training with 3 sets ranging from 10 repetitions, for all main muscle groups. In addition, all patients were encouraged to increase daily physical activities, mainly brisk walking and climbing stairs.

Nutrition interventions were performed in a 2 hour session aimed to achieve a lifestyle score greater than 12 based on Diabetes Nutrition and Complications Trial (DNCT) previously reported.

Women will be follow-up yearly during 3 years with an OGTT with 75 g, and insulin and cytokines plasma values, body weight, waist circumference and blood pressure values will be performed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Estimation of the conversion rate to abnormal glucose tolerance (type 2 diabetes mellitus, IFG and IGT) of women with prior gestational diabetes mellitus (GDM) and normal fasting glucose values after delivery, measured yearly.

Secondary outcome measures
Estimation of the changes in:
1. HbA1c
2. Insulin

3. Homestatic model assessment (HOMA)
4. Total (high density lipoprotein [HDL] and low density lipoprotein [LDL]) cholesterol
5. Triglycerides
6. Apolipoprotein B
7. Cytokines
8. Body weight
9. Waist circumference
10. Blood pressure
11. Adherence to changes in lifestyle

All outcomes are measured yearly.

Overall study start date
01/01/2006

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Women diagnosed with gestational diabetes mellitus between 24 and 28 weeks of gestation by Couston and Carpenter criteria between January 2006 and December 2007
2. Normal fasting glucose values (less than 100 mg/dl) between 8 - 12 weeks after delivery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
250

Key exclusion criteria
1. Fasting glucose level greater than 100 mg/dl between 8 - 12 weeks after delivery
2. New gestation during 3-years follow-up

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2010

Locations

Countries of recruitment

Spain

Study participating centre
Endocrinology and Nutrition Department
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Sponsor information

Organisation
St Carlos Hospital (Hospital Clínico San Carlos) (Spain)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04d0ybj29

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Spain) - Cohesion Funds 2006

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No