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Probiotics in Pregnancy Study (ProP Study)

Submission date
15/02/2012

Recruitment status
No longer recruiting

Registration date
09/03/2012

Overall study status
Completed

Last Edited
10/06/2015

Condition category
Pregnancy and Childbirth

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and aims
Raised blood sugar levels and gestational diabetes are common complications in pregnancy, particularly as overweight and obesity levels are increasing among women before entering pregnancy. Probiotics are food supplements containing beneficial bacteria and recent research has found that taking probiotics may help to control blood sugar levels in pregnant and non-pregnant women. The aim of our study is to investigate whether taking a daily probiotic supplement will reduce blood sugar levels among obese pregnant women and pregnant women with gestational diabetes mellitus (GDM).

Who can participate?
To take part in the study you need to be female and pregnant, have an early-pregnancy body mass index (BMI) between 30.0 and 39.9 Kg/m2 OR have received a new diagnosis of gestational diabetes (GDM) in your current pregnancy, be aged between 18 and 45 years, have a singleton pregnancy (not twins)

What does the study involve?
This study involves two separate parts - Part A and Part B.
Part A involves obese pregnant women (early-pregnancy BMI between 30.0 and 39.9 Kg/m2). You will be asked to take either a daily probiotic or placebo (contains no proiotic) capsule from 24 to 28 weeks of your pregnancy. The capsules will be provided to you free of charge. At 24 weeks, before starting the capsules, you will have a fasting blood sample taken to measure your blood sugar levels. At the end of the 28 weeks when you finish the capsules, you will have another fasting blood sample taken. At this stage, you will also be tested for diabetes. For the test, you will be given a sugary drink and have your blood sugar levels measured every hour for three hours after taking the drink. If the test is positive for diabetes, you will be immediately referred to the diabetic team in the hospital for the remainder of your pregnancy care. If the test is negative for diabetes, you will continue with your routine antenatal care but will be screened again for diabetes at 34 weeks. As part of this study, you will also be asked to complete a lifestyle questionnaire and a food diary. The purpose of the food diary is to record all the foods and drinks you take over three days in your pregnancy. This will be explained to you by the research dietitian. At delivery, blood will be taken from your baby's cord and your baby will be weighed and measured.
Part B of the study involves women who have recently received a new diagnosis of gestational diabetes. This diagnosis is usually made around 29-33 weeks into your pregnancy. You will be

asked to take either a daily probiotic or placebo capsule from the time you are recruited until the end of your pregnancy. The capsules will be provided to you free of charge. Throughout this time, your blood sugar levels will be closely monitored by the researchers and the diabetes clinical staff, which is part of routine care for diabetic women in pregnancy. Before you begin taking the capsules and approximately four weeks after starting on them, fasting blood samples will be taken. As part of this study, you will also be asked to complete a food diary. The purpose of the food diary is to record all the foods and drinks you take over three days in your pregnancy. This will be explained to you by the research dietitian. At delivery, blood will be taken from your baby's cord and your baby will be weighed and measured.

What are the possible benefits and risks of participating?
If you participate in Part A of the study, you will receive dietary advice from a dietitian and will receive an extra scan of your baby at 34 weeks. Neither of these are part of the routine care for non-diabetic pregnant women in Ireland. If you participate in Part B of the study, you will also receive dietary advice from a dietitian and a scan of your baby at 34 weeks, although these are part of routine antenatal care for diabetic women. There are no risks associated with this study. Probiotics have repeatedly been shown to be completely safe to take during pregnancy, with no risks for mother or baby.

Where is the study run from?
The PIP Study is taking place in the National Maternity Hospital, Holles Street, Dublin 2, Ireland.

When is the study starting and how long is it expected to run for?
The study is starting in February-March 2012 and is expected to end by December 2013.

Who is funding the study?
The study is funded by the Ivo Drury Award and The National Maternity Hospital Medical Fund, Dublin, Ireland.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
A randomised controlled trial of probiotics in pregnancy to reduce maternal glucose in obese and gestational diabetic women

Acronym
ProP

Study objectives
Taking a daily probiotic capsule during pregnancy will:
1. Reduce fasting glucose in women BMI >30kg/m2
2. Reduce fasting glucose in women with newly diagnosed gestational diabetes mellitus (GDM)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the National Maternity Hospital, Dublin, Ireland, 30/11/2011
2. Life Sciences Ethics Committee of University College Dublin, 08/12/2011 ref: LS-E-11-167 McAuliffe-Brennan

Primary study design
Interventional

Study design
Single-centre double-blind placebo-controlled randomised trial consisting of two study arms

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnancy, obesity, gestational diabetes mellitus

Interventions
Part A - Prevention of GDM:
1. At recruitment (<22 weeks gestation):
1.1. Written informed consent obtained
1.2. Weight, height, early pregnancy BMI recorded
1.3. Healthy eating dietary advice provided by research dietitian
2. At 24 weeks:
2.1. Fasting blood samples for measurement of glucose
2.2. Randomisation and commencement of probiotic/placebo capsules
2.3. Issue and explanation of 3-day food diary - to record all food and drink consumed over 3 days of the intervention period
2.4. Lifestyle questionnaire
2.5. Maternal weight recorded

3. Weeks 25-27:
3.1. Weekly monitoring of compliance to probiotic/placebo
3.2. Return of completed food diary and questionnaire
4. At 28 weeks:
4.1. Complete daily probiotic/placebo intervention
4.2. Maternal weight recorded
4.3. Fasting blood sample for measurement of glucose
4.4. 3-hour 100g oral glucose tolerance test to test for GDM
5. At 34 weeks:
5.1. Fetal ultrasound
5.2. Maternal weight recorded
5.3. 50g glucose challenge test - for women previously diagnosed as negative for GDM
6. At delivery:
6.1. Neonatal head circumference, length, weight, birth weight centile

Part B Treatment of GDM
1. At diagnosis (29-33 weeks gestation):
1.1. Written informed consent obtained
1.2. Weight, height, early pregnancy BMI recorded
2. At next clinic appointment:
2.1. Fasting blood sample for measurement of glucose
2.2. Randomisation and commencement of daily probiotic/placebo
2.3. Issue and explanation of 3-day food diary
3. At subsequent clinic appointments:
3.1. Monitor compliance to probiotic/placebo capsules
3.2. Monitor insulin requirements
3.3. Return of completed food diary
3.4. Maternal weight recorded
4. At approx. 34 weeks:
4.1. Fetal ultrasound (part of routine care for diabetic women)
5. Four weeks post start of intervention:
5.1. Fasting blood samples for measurement of glucose
6. At delivery:
6.1. Neonatal head circumference, length, weight, birth weight centile

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Obese pregnant mothers (Part A):
Difference between the control and probiotic groups in fasting blood glucose

Gestational diabetes (Part B):
Difference between the control and probiotic groups in fasting blood glucose

Key secondary outcome(s)

Part A - differences between the 2 groups:
1. Incidence of gestational diabetes
2. Neonatal anthropometry

Part B are the following differences between the 2 groups:
1. Requirement for insulin
2. Gestation at commencement of insulin and amount of insulin required
3. Neonatal anthropometry

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 30/07/2012:
Part A - prevention of GDM:
1. BMI between 30.0 and 39.9 Kg/m2
2. Gestational age ≤ 22 weeks
3. Age 18 - 45 years
4. Adequate understanding of the English language

Part B - treatment of GDM:
1. BMI in any category
2. Gestational age <36 weeks
3. New diagnosis of GDM or impaired glucose tolerance (IGT)
4. Age 18 - 45 years
5. Adequate understanding of the English language

Previous inclusion criteria until 30/07/2012:
Part B - treatment of GDM:
3. New diagnosis of GDM (not in previous pregnancy)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
Part A - prevention of GDM:
1. BMI <30.0 or >39.9 Kg/m2

2. Age <18 or >45 years
3. Gestational age >22 weeks
4. Foetal anomaly
5. Twin pregnancy
6. Inadequate understanding of English
7. Diabetes - type 1, type 2, newly diagnosed GDM or previous GDM

Part B - treatment of GDM:
Age <18 or >45 years
1. Gestational age >36 weeks
2. Foetal anomaly
3. Twin pregnancy
4. Inadequate understanding of English
5. GDM diagnosis in previous pregnancy or type 1 or 2 diabetes

Date of first enrolment
20/02/2012

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Ireland

Study participating centre
National Maternity Hospital
Dublin
Ireland
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Sponsor information

Organisation
National Maternity Hospital (Ireland)

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Maternity Hospital Medical Fund, Dublin (Ireland)

Results and Publications

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	01/06/2014		Yes	No
Results article	results	01/04/2015		Yes	No