

The DALI Study: Vitamin D and Lifestyle Intervention for Gestational Diabetes Mellitus Prevention

on the NIHR / Wellcome Trust Clinical Research Facility, Cambridge

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Background

Gestational diabetes mellitus (GDM) is an increasing problem world-wide. It may have serious consequences for mothers and babies.

What is GDM and does it matter?

GDM is 'carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy'. GDM is associated with a number of adverse perinatal outcomes (including intra-uterine death, macrosomia, neonatal metabolic abnormalities, Caesarean section, and pregnancy-induced hypertension) and longer term morbidities in both mother and child.

Aim

To compare the impact of different lifestyle strategies on the risk of developing GDM in women with BMIs greater than 29 kg/m².

DALI Research Midwives Anthropometry Standardisation workshop, Cambridge, on 20.6.13 with Mother and Baby 10, born 17.1.13.



Methodology

DALI is a multicentre, randomised trial across 11 centres in 9 European countries. The study comprised one pilot trial and two RCTs – which tested and compared three interventions: healthy eating, physical activity, and/or giving Vitamin D.

440 women were recruited to each RCT, giving a total of 880 women overall. Each participant was closely monitored by blood tests, questionnaires, measurements and additional fetal ultrasound scans according to the study schedule for approximately 7 months.



DALI Research Midwives Anthropometry Standardisation workshop, Cambridge 20.6.13 with Mother and Baby 11, born 6.1.13.



Baby 88, born 21.8.14

Schedule of Visits for Assessment and Lifestyle Intervention

1. Blood samples to be collected in the fasting state and at 0, 30, 60, 90 and 120 minutes following ingestion of the glucose drink
2. Blood to be tested locally to diagnose GDM and hypercalcemia and centrally for a range of other biomarkers.
3. Urinary calcium/creatinine to be measured locally to diagnose hypercalcaemia which is an exclusion criteria.
4. A range of maternal anthropometric measures and blood pressure taken and questionnaires completed.
5. 5 face-to-face visits and 4 telephone discussions with lifestyle coach supporting healthy eating, physical activity or both for women in intervention group.
6. Increased Vitamin D supplementation or placebo for women in relevant randomisation groups.
7. Accelerometer used for 3 days on 3 occasions alongside a food diary.
8. Wide range of neonatal anthropometric measurements taken within 72 hours of birth.

References: Simmons D (2013) DALI: Vitamin D and lifestyle intervention for gestational diabetes mellitus (GDM) prevention: an European multicentre, randomised trial – study protocol, *Biomed Central-Pregnancy and Childbirth*, 142 <http://www.biomedcentral.com/1471-2393/13/142>

Cheung NW, Blyth K (2003) Population health significance of gestational Diabetes. *Diab Care* 26: 2005-2009

Role of the Cambridge Clinical Research Facility

In the past two years the Cambridge CRF provided a safe, clinical environment for the study visits by the 128 pregnant participants of the trial (three visits per participant).

The CRF nursing staff assisted with cannulation for Oral Glucose Tolerance Tests (OGTTs), blood sampling and close monitoring throughout each visit, as well as providing meals.

Study support

The study was funded by European Union Commission, Framework VII (FP7/2007-2013) Grant Agreement no. 242187



Results

Different degrees of weight gain were found with the different interventions, weight gain increased after 28/52 and many women were able to restrict their weight gain to the target of 5kg. Analyses is ongoing (recruitment is continuing at some EU sites) and results will be published during 2015 and 2016.

Discussion

It is anticipated that findings from the DALI study will be translated into NICE and European standards for antenatal care and also direct future research to ensure that women with raised BMIs across Europe receive effective support to prevent GDM.

Contacts

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