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A nutritional supplement for better breastfeeding?

Submission date
16/07/2020

Recruitment status
No longer recruiting

Registration date
28/10/2020

Overall study status
Completed

Last Edited
30/12/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Breastfeeding has health benefits for both mother and baby. Women who develop diabetes in pregnancy (also known as gestational diabetes) have a higher chance of developing Type 2 diabetes in later life. Breastfeeding reduces this risk. Women who have diabetes in pregnancy are more likely to have problems with lower levels of breastmilk being made and this is a common reason for stopping breastfeeding in Ireland. Fenugreek is a herb used in Asian cooking. It is used in traditional medicine to treat diabetes. It is often recommended to improve the amount of breastmilk being made. The aim of this study is to test whether fenugreek can improve the amount of breastmilk being made in women who had a pregnancy with gestational diabetes. The researchers also want to find out if it works by changing the way the woman's body responds to the levels of glucose or sugar in the blood.

Who can participate?
Pregnant women with diabetes in pregnancy, after they have given birth

What does the study involve?
The study will involve taking a one-month supply of fenugreek capsules. The researchers will take some measurements of the mothers and babies in the postnatal ward. They will measure their weight and height and check the baby's weight, length and head measurement. Mothers will have a blood test after they deliver to check their blood glucose/sugar level while they are fasting. The researchers will show them how to weigh their baby before and after every feed, for 24 hours. This allows them to measure how much milk the baby has had in those 24 hours. The researchers will do this during the mothers' time in hospital after they give birth. This weighing will be repeated for another 24 hours, after the 28 days of taking the supplement. Mothers will be given weighing scales for this, which will be collected after the study. The researchers will also ask them to provide a small sample of breastmilk at the end of the study. Mothers will come back to the hospital at 6 weeks after delivery for their glucose test as normal. The researchers will take one extra blood sample at this visit. Mothers will also be asked to give a short telephone interview, where the researchers will ask about their experience of taking part in the study.

What are the possible benefits and risks of participating?
The mothers might benefit from participating but this is not guaranteed. The idea is that the supplement will help them make more breastmilk, which may help them breastfeed their child. The researchers hope to gain knowledge which will benefit future medical care as well. If this study shows that taking a daily fenugreek supplement while breastfeeding results in a more breastmilk production then this may be a safe way to improve the amount of breastmilk being produced in women at risk of low breastmilk production in the future. Mothers may find that remembering to take the supplement twice a day for 28 days, providing a breastmilk sample and completing the weighing of your baby before and after every breastfeed for 2 days inconvenient. Providing the additional blood sample at the start and end of the study may cause mild discomfort. Fenugreek is widely used as a cooking ingredient. When taken as a supplement it generally does not cause any problems but side effects such as nausea, vomiting and diarrhoea may occur. The most common side effect is a smell of maple syrup to the urine, sweat, faeces and breastmilk. This is not harmful and will stop after you stop taking fenugreek. Mothers should not take fenugreek if they have an allergy to peanuts, chickpeas or other legumes as they may also be allergic to fenugreek.

Where is the study run from?
University College Dublin (UCD) (Ireland)

When is the study starting and how long is it expected to run for?
July 2019 to February 2022

Who is funding the study?
University College Dublin (UCD) (Ireland)

Who is the main contact?
Dr Niamh Keating
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Contact information

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Scientific

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Additional identifiers

Study information

Scientific Title
A nutritional supplement (Fenugreek) for improved breastfeeding outcomes in women at risk of low breastmilk supply

Study objectives
The nutritional supplement Fenugreek is an effective and tolerable galactagogue in women with gestational diabetes intending to breastfeed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/12/2019, National Maternity Hospital Ethics Committee (Holles St, Dublin 2, Ireland; +353 (0)1 6373588; ethicsresearch@nmh.ie), ref: EC32.2019

Study design
Prospective open-label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low breast milk supply in women with gestational diabetes mellitus

Interventions
Eligible participants will be asked to take a 28-day supply of the food supplement Fenugreek. 7.5 g Fenugreek seed extract (FSE) powder provided as 938 mg 8:1 concentrated FSE. At baseline, prior to commencing treatment, the women will be asked to weigh their babies before and after every feed for a 24-hour period. This gives a measure of the amount of milk consumed by the infant in that time. This will be repeated after the treatment course. In addition, maternal and

infant biometric data will be collected and a fasting glucose blood sample from the mother at baseline and after the treatment course. The woman will also complete a glucose tolerance test at 6 weeks post-partum. During the treatment phase, participants will keep a symptom diary. A sample of breastmilk will be obtained after completion of the course of supplements for transcriptome and metabolomic analysis. Metabolomic profiles will be acquired using a 600 MHz NMR spectrometer. NMR allows detection and quantification of the most abundant metabolites present in biological samples. MS coupled with liquid or gas chromatography techniques will be used to target specific groups of metabolites including but not limited to fatty acids and amino acids. The transcriptome analysis and the NMR metabolomics will inform the targeted approach for MS metabolomics. The combined use of NMR and MS techniques allows for more comprehensive coverage of the breastmilk composition. After completion of the study, participants will be asked to take place in a telephone interview to share their experience of taking part in the trial.

Intervention Type
Supplement

Primary outcome(s)
1. Breast milk composition measured using metabolomics and transcriptome analysis (NMR and MS) after the supplement course (28 days)
2. Breastfeeding self-efficacy measured using Breastfeeding Self Efficacy Scale Short Form at 28 days
3. Blood biomarkers: glucose and blood lipids measured using the Randox Daytona autoanalyzer, insulin and adiponectin measured using ELISA techniques at 6 weeks postpartum

Key secondary outcome(s))
1. Information on breastfeeding history collected by questionnaire at the time of recruitment
2. Anthropometric measured at Day 1 postnatal:
2.1. Mother: weight (kg), height (cm), calculated BMI (weight/height in metres squared)
2.2. Infant: birth weight (g), length (cm), head circumference (cm) and plotted on WHO centiles (%)
3. Symptoms related to fenugreek use measured using diary at weekly intervals for 28 days
4. Compliance measured using returned pill boxes at the end of the supplement course (28 days)
5. Maternal experience interview using qualitative analysis methods at the end of the trial (28 days)

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Recent pregnancy affected by gestational diabetes mellitus
2. Intention to breastfeed for at least the trial period of 4 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
41

Key exclusion criteria
1. Age <18
2. Pre-existing diabetes
3. Low birth weight <2.5 kg
4. Congenital anomalies
5. Low Apgar score
6. NICU admission
7. Breastfeeding not recommended e.g. maternal HIV infection

Date of first enrolment
01/09/2020

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
Ireland

Study participating centre
UCD Perinatal Research Centre
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Sponsor information

Organisation
University College Dublin

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Niamh Keating (niamh.keating@ucdconnect.ie).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V3		18/05/2021	No	No