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Effect of Caffeine on Gestational Diabetes Screening

Submission date	Recruitment status	[_] Prospectively registered
27/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/01/2021	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
Effect of Caffeine on Gestational Diabetes Screening

Study objectives
We hypothesize that maternal caffeine ingestion has an adverse impact on screening for Gestational Diabetes Mellitus (GDM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

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

Interventions
Effect of Caffeine versus placebo on 75 g oral glucose tolerance test results

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Caffeine

Primary outcome measure
Maternal blood glucose

Secondary outcome measures
1. Maternal plasma insulin, C-peptide, catecholamines, methylxanthines, free fatty acids, glycerol, lactate, and electrolytes
2. Fetal heart rate baseline and accelerations

Overall study start date
01/10/2005

Completion date
30/12/2005

Eligibility

Key inclusion criteria
1. Pre-pregnancy body mass index (BMI) less than 30 kg/m^2
2. Non-smoking
3. No medications that could interfere with glucose uptake/metabolism (i.e. insulin, anti-hyperglycemics)
4. No known medical/obstetrical complications

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
30

Total final enrolment
27

Key exclusion criteria
As per inclusion criteria

Date of first enrolment
01/10/2005

Date of final enrolment
30/12/2005

Locations

Countries of recruitment
Canada

Study participating centre
Department of Obstetrics & Gynecology
Kingston
Canada
K7L 2V7

Sponsor information

Organisation
Canadian Foundation for Women's Health

Sponsor details
78 Echo Drive
Ottawa
Canada
K1S5R7
+1 6137304192
kmacgowan@sogc.com

Sponsor type
Charity

Website
http://www.cfwh.org/index_e.html

ROR
https://ror.org/0278syk25

Funder(s)

Funder type
Charity

Funder Name
Canadian Foundation for Women's Health

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	01/04/2009	12/01/2021	Yes	No