

Effect of Caffeine on Gestational Diabetes Screening

Submission date
27/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/11/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
12/01/2021

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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/m²
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