# Effect of Caffeine on Gestational Diabetes Screening

| Submission date   | Recruitment status                | <ul><li>Prospectively registered</li></ul> |  |
|-------------------|-----------------------------------|--|--|
| 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

#### Contact name

Dr Graeme Smith

#### Contact details

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## Additional identifiers

Protocol serial number

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

## Study type(s)

Screening

## 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(s)

Maternal blood glucose

## Key secondary outcome(s))

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

## 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, antihyperglycemics)
- 4. No known medical/obstetrical complications

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

Female

## 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

**ROR** 

# Funder(s)

## Funder type

Charity

## Funder Name

Canadian Foundation for Women's Health

## **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 | 01/04/2009   | 12/01/2021 | Yes            | No              |