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# A Randomized Cross Over Trial Of Tolerability And Compliance Of A Supplement With Low Iron Separated From Calcium Versus High Iron Combined With Calcium In Pregnant Women

**Submission date**
25/10/2005

**Recruitment status**
No longer recruiting

**Registration date**
01/11/2005

**Overall study status**
Completed

**Last Edited**
03/10/2017

**Condition category**
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Gideon Koren

**Contact details**
555 University Ave
Toronto, Ontario
Canada
M5G 1X8
+1 416 813 5781
gkoren@sickkids.ca

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

1000005135

# Study information

### Scientific Title
A Randomized Cross Over Trial Of Tolerability And Compliance Of A Supplement With Low Iron Separated From Calcium Versus High Iron Combined With Calcium In Pregnant Women

### Study objectives
The lower amounts of iron in PregVit as compared to Materna will result in lower rates of adverse effects (mainly nausea and constipation) among pregnant women

### 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)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Pregnancy

### Interventions
A prospective, randomized, open labeled, cross over study of PregVit versus Materna

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
PregVit and Materna

### Primary outcome measure
To compare the tolerability and adverse effects of PregVit versus Materna.

### Secondary outcome measures
A comparison of patients' compliance measured by pill counts of PregVit versus Materna

### Overall study start date
07/01/2003

### Completion date
05/05/2004

## Eligibility

### Key inclusion criteria
Pregnant women between 18 and 45 years of age.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Female

### Target number of participants
100

### Key exclusion criteria
1. Pregnant women with insufficient English language skills to understand the questions
2. Pregnant women who refuse to participate in our study
3. Chronic illness
4. Current acute illness and known allergies to either Materna or PregVit

### Date of first enrolment
07/01/2003

### Date of final enrolment
05/05/2004

## Locations

### Countries of recruitment
Canada

**Study participating centre**
**555 University Ave**
Toronto, Ontario
Canada
M5G 1X8

# Sponsor information

**Organisation**
Duchesnay Inc (Canada)

**Sponsor details**
2925 Industrial blvd
Laval, Quebec
Canada
H7L 3W9
+1 450 668 5200
sgargaun@duchesnay.com

**Sponsor type**
Industry

**Website**
http://www.duchesnay.com

**ROR**
https://ror.org/03v67de52

# Funder(s)

**Funder type**
Industry

**Funder Name**
Duchesnay Inc

# 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 | 04/04/2006 | | Yes | No |