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	Recruitment status No longer recruiting	Prospectively registered		
25/10/2005		☐ Protocol		
Registration date 01/11/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
03/10/2017	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

To compare the tolerability and adverse effects of PregVit versus Materna.

Key secondary outcome(s))

A comparison of patients' compliance measured by pill counts of PregVit versus Materna

Completion date

05/05/2004

Eligibility

Key inclusion criteria

Pregnant women between 18 and 45 years of age.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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)

ROR

Funder(s)

Funder type

Industry

Funder Name

Duchesnay Inc

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	04/04/2006		Yes	No