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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