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Optimizing periconceptional and prenatal folic acid supplementation

Submission date
11/03/2013

Recruitment status
No longer recruiting

Registration date
09/04/2013

Overall study status
Completed

Last Edited
09/04/2013

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We wish to measure red blood cell and serum folate concentrations among women who are healthy and/or childbearing age, those planning a pregnancy or early in pregnancy (< 6 weeks gestation) and who do not practice multivitamin supplementation. We would like to measure and compare folate levels among women before and after implementing multivitamin supplementation with either PregVit® or PregVit-Folic 5®. This may be important information for planning or pregnant women who need folic acid, which has been shown to reduce the risk of neural tube defects and potentially other malformations as well.

Who can participate?
Women who are healthy and/or childbearing age, those planning a pregnancy or early in pregnancy (< 6 weeks gestation) and who do not take vitamin supplements.

What does the study involve?
Participants are randomly allocated to one of two groups: PregVit-Folic 5® (group1) contains 5 mg folic acid or PregVit® (group 2) contains 1.1 mg folic acid. All other vitamin and mineral doses are identical between the 2 supplements. Both supplements are taken as 2 tablets daily, one tablet in the morning (am) and one tablet in the evening (pm). Both multivitamins are appropriate for periconceptional, prenatal, and post-partum supplementation.
The total volume of blood that will be taken is approximately 20 mL (4 teaspoons). Each appointment will be scheduled according to when participants are available. To monitor adherence, the PregVit-Folic 5® blister packs should be returned among with a diary of pill intake (will be provided). To document dietary folate, telephone interviews regarding the diet will be conducted.

What are the possible benefits and risks of participating?
Daily multivitamin supplementation can improve vitamin and mineral concentrations. We will be able to tell participants about folate blood level. Results can be disclosed in person or by mail. High doses of folic acid can mask vitamin B12 deficiency. However, this is generally not a concern for healthy individuals, with no chronic medical conditions. One study has shown that vitamin B12 deficiency can still be detected even with high folate blood concentrations. PregVit® and PregVit-Folic 5® both contain vitamin B12, thus it is being supplemented. Furthermore, vitamin

B12 blood concentrations will be measured alongside folate blood concentrations to monitor for deficiencies.
The needle poking may not be pleasant. We will offer a cream named EMLA® to massage on the arm, which takes away much (sometimes all) of the pain of poking. An alternative that can be used is a gel named Ametop®.

Where is the study run from?
The study took place at The Hospital for Sick Children in Toronto, Canada.

When is the study starting and how long is it expected to run for?
The study started in 2007 and was completed in 2013.

Who is funding the study?
Duchesnay Inc. (Blainville, Quebec, Canada).

Who is the main contact?
Dr. Gideon Koren
gkoren@sickkids.ca

Contact information

Type(s)
Scientific

Contact name
Dr Gideon Koren

Contact details
Hospital for Sick Children
555 University Avenue
Toronto
Canada
M5X1X8

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Optimizing periconceptional and prenatal folic acid supplementation: Red Blood Cell and Serum Folate Levels Achieved with 5 mg versus 1.1 mg Folic Acid in Prenatal Multivitamin-Mineral Supplements

Study objectives
To assess the serum folate pharmacokinetics of ingesting a single dose of PregVit-Folic5® versus a single dose of PregVit® (a multivitamin containing 1.1 mg folic acid); to assess the steady-state red blood cell (RBC) and serum folate concentrations achieved in non-pregnant,

fertile women who supplement daily with PregVit-Folic5® versus PregVit®; and to assess the steady-state RBC and serum folate concentrations achieved before and during pregnancy in women planning a pregnancy or early in pregnancy (<6 weeks gestation) who supplement daily with PregVit-Folic5® versus PregVit®. The Study hypotheses are as follows:
1. The serum folate concentration from ingesting PregVit-folic 5® (5 mg folic acid) will be 4-5 fold larger compared to that of PregVit® (1.1 mg folic acid).
2. Non-pregnant women of childbearing age who supplement daily with PregVit-folic 5® will invariably and optimally achieve and maintain maximum protective blood folate levels (i.e. ≥900 nM red blood cell folate) against NTDs.
3. Women planning a pregnancy or early in pregnancy (<6 weeks gestation) who supplement daily with PregVit-folic 5® will invariably and optimally achieve and maintain maximum protective blood folate levels (i.e. ≥ 900 nM red blood cell folate) against NTDs before and during pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Hospital for Sick Children, March 2007, REB #: 1000009554

Study design
Prospective randomized two-arm interventional study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Multivitamin supplementation in pregnancy

Interventions
This is a two-arm comparison study: PregVit-Folic 5® (arm 1) contains 5 mg folic acid and PregVit® (arm 2) contains 1.1 mg folic acid. All other vitamin and mineral doses are identical between the 2 supplements. Both supplements are taken as 2 tablets daily, one tablet in the morning (am) and one tablet in the evening (pm). Both multivitamins are appropriate for periconceptional, prenatal, and post-partum supplementation. For the single dose study, only 1 dose was taken. For the multiple dose study, supplementation continued for 30 weeks.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Folic acid

Primary outcome(s)

1. To assess the serum folate pharmacokinetics in healthy, non-pregnant women of childbearing age who ingest a single evening dose of PregVit-folic 5® (5 mg folic acid) versus a single evening dose of PregVit® (1.1 mg folic acid).
2. To assess steady-state red blood cell and serum folate levels achieved in healthy, non-pregnant women of childbearing age who supplement daily for 30 weeks with PregVit-folic 5® versus PregVit®.
3. To assess the steady-state periconceptional and gestational red blood cell and serum folate levels in women planning a pregnancy or early in pregnancy (<6 weeks gestation) who supplement daily with PregVit-folic 5® versus PregVit®.

For the single dose study, extensive blood sampling was conducted over 12 hours.

For the multiple dose study, blood sampling was conducted as follows:

Return to research site at 6 weeks gestation to draw one blood sample. Pick up next supply of multivitamins (hospital pharmacy).

Return to research site at 12 weeks gestation to draw one blood sample. Pick up next supply of multivitamins (hospital pharmacy).

Return to research site at 30 weeks gestation to draw last blood sample.

Key secondary outcome(s))
To assess adherence and tolerability of the prenatal mutlivitamins

Completion date
01/07/2013

Eligibility

Key inclusion criteria
Women planning a pregnancy, or women less than 6 weeks pregnant who are not using a prenatal mutlivitamin

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Women who are already taking a prenatal multivitamin.
2. Women who are allergic to any of the ingredients in PregVit or PregVit Folic 5.
3. Women with iron disorders.

Date of first enrolment
01/03/2007

Date of final enrolment
01/07/2013

Locations

Countries of recruitment
Canada

Study participating centre
Hospital for Sick Children
Toronto
Canada
M5X1X8

Sponsor information

Organisation
Duchesnay Inc. (Canada)

ROR
https://ror.org/03v67de52

Funder(s)

Funder type
Industry

Funder Name
Duchesnay Inc. (Canada)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes