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Oral magnesium for relief in pregnancy-induced leg cramps

Submission date
08/11/2011

Recruitment status
No longer recruiting

Registration date
14/11/2011

Overall study status
Completed

Last Edited
22/09/2016

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
Leg cramps are common for pregnant women; 30-45% of pregnant women suffer from leg cramps. Pregnancy-induced leg cramp tends to be more frequent during the second half of pregnancy, and mostly at night, resulting in sleep disruption which potentially introduces other complications. Currently, there is no standard treatment for pregnancy-induced leg cramps; however several studies have been conducted so far. Magnesium seems to be beneficial in the treatment of pregnancy-induced leg cramps. Shortage of magnesium may be why there is a higher rate of leg cramps in pregnancy. There have been few studies of magnesium for the treatment of leg cramps in pregnancy. The aim of this study is to assess the effectiveness of magnesium biglycinate chelate as a treatment for pregnancy-induced leg cramps.

Who can participate?
Pregnant women who have pregnancy-induced leg cramps at least twice a week

What does the study involve?
Participants are asked about their leg cramps and background characteristics such as age, income, education, standing or walking hours per day, BMI before pregnancy, antenatal supplement drugs, calcium supplement, blood pressure, leg edema (swelling) and varicose veins. After that participants are randomly allocated to receive either magnesium biglycinate chelate tablets or a placebo (dummy) supplement. Participants take one tablet, three times a day with a meal. The duration of treatment was 4 weeks. At the follow-up participants are asked about their leg cramps and side effects such as nausea, vomiting and diarrhea are recorded.

What are the possible benefits and risks of participating?
There may be mild nausea and diarrhea while taking the medication.

Where is the study run from?
Chulalongkorn University (Thailand)

When is the study starting and how long is it expected to run for?
June 2010 to August 2011

Who is funding the study?
Chulalongkorn University (Thailand)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A randomized, double-blinded, placebo-controlled trial of oral magnesium for relief in pregnancy-induced leg cramps

Study objectives
Oral magnesium can relieve pregnancy-induced leg cramps when compare to placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Faculty of Medicine, Chulalongkorn University, 17/06/2010, ref: 005/53

Study design
Randomized double-blinded placebo-controlled trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pregnant women with leg cramps

Interventions
Oral magnesium biglycinate chelate (300mg/day) versus placebo

Total duration of interventions is 4 weeks. Study drugs either magnesium or placebo will be administered orally at a frequency of three times a day for 4 weeks. Participants complete the follow-up case report forms (CRF) at the beginning of the 4th week and completed it at the end of the 4th week. For the follow-up CRF, leg cramps characteristics and side effects such as nausea, vomiting and diarrhea were recorded. Participants return follow-up CRF and the plastic container at the end of the 4th week.

Intervention Type
Supplement

Primary outcome(s)
50% reduction in frequency of leg cramps

Key secondary outcome(s))
1. 50% reduction of cramp intensity
2. Side effects

Completion date
31/08/2011

Eligibility

Key inclusion criteria
1. Pregnant women were those with 14-34 weeks of gestation
2. Having pregnancy-induced leg cramps at least twice a week
3. No other medical disease
4. No concurrent obstetrics complication
5. No other prescriptions for leg cramps
6. No history of magnesium allergy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Pregnant women with multifetal gestation
2. Subsequently developed pregnancy-induced hypertension and preterm labor treated with tocolytic agent

Date of first enrolment
01/06/2010

Date of final enrolment
31/08/2011

Locations

Countries of recruitment
Thailand

Study participating centre
Chulalongkorn University
Bangkok
Thailand
10330

Sponsor information

Organisation
Chulalongkorn University (Thailand)

ROR
https://ror.org/028wp3y58

Funder(s)

Funder type
University/education

Funder Name
Chulalongkorn University (Thailand)

Alternative Name(s)

, CU, Chula

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Thailand

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration