

Oral magnesium for relief in pregnancy-induced leg cramps

Submission date 08/11/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/11/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/09/2016	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English Summary

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?
Dr Vorapong Phupong
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

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

Study hypothesis
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Condition

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 measure

50% reduction in frequency of leg cramps

Secondary outcome measures

1. 50% reduction of cramp intensity
2. Side effects

Overall study start date

01/06/2010

Overall study end date

31/08/2011

Eligibility

Participant 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

Age group

Adult

Sex

Female

Target number of participants

86

Participant exclusion criteria

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

Recruitment start date

01/06/2010

Recruitment end date

31/08/2011

Locations

Countries of recruitment

Thailand

Study participating centre

Chulalongkorn University

Bangkok

Thailand

10330

Sponsor information

Organisation

Chulalongkorn University (Thailand)

Sponsor details

Faculty of Medicine
Rama IV Road
Pathumwan
Bangkok
Thailand
10330

Sponsor type

University/education

Website

<http://www.chula.ac.th/cuen/>

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

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