# Oral magnesium for relief in pregnancy-induced leg cramps

Submission date 08/11/2011	<b>Recruitment status</b> No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 14/11/2011	Overall study status Completed	Statistical analysis plan
		Results
Last Edited	Condition category	Individual participant data
22/09/2016	Pregnancy and Childbirth	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? Dr Vorapong Phupong vorapong.p@chula.ac.th

## Contact information

#### Type(s)

Scientific

#### Contact name

**Prof Vorapong Phupong** 

#### Contact details

Department of Obstetrics and Gynecology Faculty of Medicine Chulalongkorn University Rama IV Road Pathumwan Bangkok Thailand 10330

vorapong.p@chula.ac.th

## 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 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

#### 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

#### 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 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

## Completion date

# **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** 

#### Age group

Adult

#### Sex

Female

## Target number of participants

86

#### 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)

#### 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