ISRCTN03989660 https://doi.org/10.1186/ISRCTN03989660

# 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?
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

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

### 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