

Pharmacokinetics profile of magnesium after intravenous and intramuscular magnesium sulfate administration in Indonesian pregnant women with pre-eclampsia

Submission date 23/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/08/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Pre-eclampsia is a potentially serious condition affecting pregnant women, usually during the second half of pregnancy or just after the baby is born. Symptoms include high blood pressure, protein in the urine, swelling of feet, ankles, face and hands, severe headache, vision problems and pain experienced below the ribs. If not treated, eclampsia may develop. Eclampsia is a type of fit, or seizure. This carries with it a small risk of permanent disability or brain damage if the fits are severe. Women with pre-eclampsia can be prescribed magnesium sulphate. This drug can help prevent seizures in women with severe pre-eclampsia and decrease them in women with eclampsia. Drugs can be absorbed, distributed, metabolised and excreted (removed) by the body differently according to how it is given to the patient. This is called the drug pharmacokinetic profile. This study is looking at the pharmacokinetics profile of magnesium sulphate (MgSO₄) given directly into the muscle (intramuscular) compared to the drug given into a vein (intravenous).

Who can participate?

Patients with preeclampsia from Subang District Hospital.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are given an initial MgSO₄ "loading dose" (higher starting dose) intravenously (IV) followed by a IV maintenance dose. Those in group 2 are given a IV plus intramuscular (IM) loading dose followed by a IM maintenance dose that is given every 4 hours. The therapy in both groups are stopped at 24 hours. Blood samples are collected at the start of the treatment and then after 10 minutes, 1 hour, 2 hours, 4 hours, 24 hours, 26 hours, 28 hours, and finally 30 hours after treatment begins. Serum magnesium levels are determined in the laboratory. The pharmacokinetics profiles of magnesium for each group are obtained and compared.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Subang District Hospital (Indonesia)

When is the study starting and how long is it expected to run for?
June 2012 to July 2014

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Lily Marliany Surjadi (public)
2. Professor Mustofa Jogja (scientific)

Contact information

Type(s)

Public

Contact name

Dr Lily Marliany Surjadi

Contact details

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55281

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Randomized clinical trial

Study information

Scientific Title

Pharmacokinetics profile of magnesium after intravenous and intramuscular magnesium sulfate administration in Indonesian pregnant women with pre-eclampsia: a randomized clinical trial

Study objectives

IM (intramuscular) and IV (intravenous) administration of magnesium sulfate in pre-eclampsia show different pharmacokinetics profile

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Medical and Health Research Ethics Committee (MHREC), Ministry of National Education, Faculty of Medicine Gadjah Mada University, ref: KE/FK/556/EC

Study design

Randomized clinical trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pre-eclampsia

Interventions

A total 70 pregnant women with pre-eclampsia were involved in this study. Subjects were divided into two groups with 35 subjects in each group. The intravenous group received an IV loading dose of MgSO₄ solution, followed by a maintenance IV regimens of MgSO₄. The intramuscular group received an IV loading dose MgSO₄ solution, followed by a IM regimens of MgSO₄. Serial blood samples were collected at 0; 10 min; 1; 2; 4; 24; 26; 28 and 30 h. The serum Mg concentrations were determined using the atomic absorption spectrophotometer method. Pharmacokinetics parameters including peak serum concentration (C_{max}), time to reach peak

concentration (Tmax), the area under the serum concentration versus time curve going to infinity (AUC_{0-∞}) and elimination half-life (t_{1/2}), elimination rate constant (kel), clearance (Cl), and volume of distribution (Vd) were calculated using standard methods and compared between groups.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Magnesium sulfate

Primary outcome measure

Serum magnesium level

Secondary outcome measures

Pharmacokinetics profile of magnesium sulfate

Overall study start date

01/06/2012

Completion date

15/07/2014

Eligibility

Key inclusion criteria

1. Single pregnancy
2. Pre-eclampsia
3. Willing to join the study

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

70

Key exclusion criteria

1. Magnesium intoxication
2. Other pregnancy complications

Date of first enrolment

01/06/2013

Date of final enrolment

15/07/2014

Locations

Countries of recruitment

Indonesia

Study participating centre

Subang District Hospital

West Java

Subang

Indonesia

41212

Sponsor information

Organisation

Faculty of Medicine, Universitas Gadjah Mada

Sponsor details

Jl. farmako - Sekip Utara

Yogyakarta

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55281

Sponsor type

University/education

Website

www.s3fk.ugm.ac.id

ROR

<https://ror.org/03ke6d638>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Dissertation at Doctoral Program, Faculty of Medicine, Universitas Gadjah Mada, Yogyakarta, Indonesia

Journal of Medical Science

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available