ISRCTN13244564 https://doi.org/10.1186/ISRCTN13244564

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

Registration date
31/08/2015

Overall study status
Completed

Last Edited
20/08/2015

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
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 prescribed magnesium sulphate. This drug can help prevent seizures in women with severe pre-eclampsia and decrease them in women with eclampsia. Drugs can been 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 level 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
Faculty of Medicine
Gadjah Mada University
jl. Farmako - Sekip
yogyakarta
Indonesia
55281

Type(s)
Scientific

Contact name
Prof Mustofa Jogja

Contact details
Bag. farmakologi
Fakultas Kedokteran Universitas Gadjah Mada
Yogyakarta
Indonesia
55281

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 diffferent 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 (Cmax), time to reach peak

concentration (Tmax), the area under the serum concentration versus time curve going to infinity (AUCo-∞) and elimination half-life (t1/2), 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
Indonesia
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