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Simplified treatment for eclampsia prevention using magnesium sulfate

Submission date
24/03/2022

Recruitment status
Recruiting

Registration date
29/07/2022

Overall study status
Ongoing

Last Edited
19/02/2026

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Pre-eclampsia and eclampsia are conditions that can develop in pregnant women. Pre-eclampsia affects around 5% of all pregnancies. Women with pre-eclampsia will have high blood pressure in addition to other symptoms like headache, abdominal (belly) pain, nausea or vomiting late in pregnancy, or severe swelling such as in the woman's hands or face. If serious the women may also have a seizure or convulsion known as eclampsia. Both pre-eclampsia and eclampsia can cause a woman to be very sick and, in some cases even die. When a women develops pre-eclampsia, a medicine called magnesium sulfate is used to prevent the woman from having serious complications including seizures (convulsions) (eclampsia).

Magnesium sulfate is widely accepted as a life-saving drug and used in many countries. Normally the magnesium sulfate is given through multiple injections into a muscle (an injection with a needle into the buttocks) or an intravenous infusion (where a small needle with a tube is inserted into a vein on the hand). Sometimes both injections into the buttocks and infusion through a vein on the hand are used. This mode of injections of magnesium sulfate is complex and therefore requires health professionals working at higher level health facilities to administer. As the administration of magnesium can require giving many injections and the woman needs to be monitored for excessive levels of magnesium in the body (magnesium toxicity), in some settings, women can only receive treatment in a hospital and not at lower level health facilities.

We are conducting a clinical trial to investigate whether a simpler regimen of giving magnesium sulfate which may involve giving fewer injections can be used to treat women with pre-eclampsia and prevent their progression to eclampsia. We aim to see if the simpler regimen also prevents seizures (convulsions) and complications in the same way that using the standard treatment does and is safe for mothers and their babies. If we find that the simpler treatment regimen is as good (or even better) than the standard treatment, then it will likely mean that more women, in more places, who need magnesium sulfate because of pre-eclampsia will be able to receive this life-saving medicine.

Who can participate?
Women admitted to hospital with pre-eclampsia and who have indications for treatment with magnesium sulfate will be invited to participate in this research.

What does the study involve?
This research will involve women with pre-eclampsia receiving either the simpler magnesium sulfate treatment regimen (two doses of 10 g administered 12 hours apart) or the standard but more complex treatment regimen (comprising several injections given both into a muscle and a vein in the hand [totally 39 g] or entirely through an infusion into a vein in the hand [totally 28 g].

What are the possible benefits and risks of participating?
In this trial, all participants will receive magnesium sulfate through injection into the buttocks, or a small needle and tube in the hand (intravenous line). The injection can cause some temporary swelling or soreness around the place where the injection goes into the buttocks or hand where intravenous line is.

There are some side effects of magnesium including flushing or sweating. If the body cannot process the magnesium well, magnesium toxicity can occur. In the case of magnesium toxicity, this can be identified by losing knee reflexes, a decrease in urinating (passing urine), or difficulty in breathing. If this happens, calcium gluconate would be given to reduce the effects of magnesium toxicity.

Having pre-eclampsia increases the risk of the woman having serious complications including seizures/convulsions and can sometimes even result in the woman dying. Having magnesium sulfate reduces the risk of having a seizure. In this research project, there is a risk that the simplified regimen of giving magnesium sulfate may not prevent a seizure as well as the standard regimen.

There is no immediate benefit to you, but the findings of this research may benefit you (or someone close to you) in a future pregnancy.

Where is the study run from?
The study is being coordinated by the Maternal Perinatal Health Team of the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Sexual and Reproductive Health and Research Department, World Health Organization, Geneva, Switzerland.

When is the study starting and how long is it expected to run for?
December 2018 to December 2028

Who is funding the study?
The study is funded by MSD (Merck Sharp and Dohme) for Mothers (USA) and the UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), a cosponsored programme executed by the World Health Organization (Switzerland)

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
A66014

Study information

Scientific Title
Simplified treatment for eclampsia prevention using magnesium sulfate: a phase III, randomised, open label, active controlled, multicountry, multicentre, non-inferiority trial of simplified magnesium sulfate regimen for eclampsia prophylaxis

Acronym
The STEP-Mag Trial

Study objectives

Current study hypothesis as of 26/10/2022:
1. Magnesium sulfate 10 g IM administered 12 hourly x 2 doses is non-inferior to standard IV (Zuspan) or IM (Pritchard) regimen in terms of the proportion of women experiencing an eclamptic seizure within a non-inferiority margin of 0.51% on the absolute risk scale
2. Magnesium Sulfate 10g IM administered 12 hourly x 2 doses is superior to standard IV (Zuspan) or IM (Pritchard) regimen in terms of the proportion of women experiencing an eclamptic seizure. Superiority of this outcome will be tested if non-inferiority has been demonstrated.
3. Magnesium sulfate 10 g IM administered 12 hourly x 2 doses is non-inferior to standard IV (Zuspan) or IM (Pritchard) regimen in terms of the proportion of women experiencing an eclamptic seizure within a less stringent non-inferiority margin of 0.85% on the absolute risk scale.

Previous study hypothesis:
1. Magnesium Sulfate 10g IM administered 12 hourly x 2 doses is non-inferior to standard IV (Zuspan) or IM (Pritchard) regimen in terms of the proportion of women experiencing an eclamptic seizure within a non-inferiority margin of 1.5 on the relative risk scale.
2. Magnesium Sulfate 10g IM administered 12 hourly x 2 doses is superior to standard IV (Zuspan) or IM (Pritchard) regimen in terms of the proportion of women experiencing an eclamptic seizure. Superiority of this outcome will be tested if non-inferiority has been demonstrated.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/02/2021, WHO Ethics Research Committee (World Health Organization, 20 Avenue Appia, 1211 Geneva, Switzerland; no telephone number provided; ercsec@who.int), ref: ERC0003614

Continuing approval received 09/12/2025.

Approvals from country sites:
1. India
Institutional Ethics Committee of KLE Academy of Higher Education and Research (approved 21 May 2021)
Institutional Ethics Committee J.J.M. Medical College (approved 28 August 2021)
Institutional Ethics Committee Riachur Institute of Medical Sciences, Riachur (approved 15 August 2021)
Gadag Institute of Medical Sciences, Institutional Ethical Committee (approved 24 September 2021)
Institutional Ethics Committee S.C.B. Medical College & Hospital, Cuttack, Odisha (approved 3 August 2021)
2. Kenya
KNH-UON Ethics &Research Committee (approved 5 October 2021)
3. Malawi
College of Medicine Research and Ethics Committee, University of Malawi (approved 4 November 2021)
4. Nigeria

Aminu Kano Teaching Hospital, Kano Research Ethics Committee (approved 13 July 2021)
5. Uganda
Makerere University, College of Health Sciences School of Medicine, Research Ethics Committee (approved 31 January 2022)
6. Rwanda
National Ethics Committee, Republic of Rwanda, Ministry of Health (approved 12 July 2021)
7. South Africa
The Research Ethics Committee, Faculty Health Sciences, University of Pretoria (approved 5 August 2021)
8. Egypt
Ains Shams University Faculty of Medicine, Research Ethics Committee (9 June 2021)

Study design
Phase III multicountry multicentre two-arm parallel open-label active-controlled randomized non-inferiority trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of eclampsia in patients with pre-eclampsia

Interventions
Experimental arm
Women in the intervention arm will receive the simplified regimen of two IM doses of 10g magnesium sulphate 12 hours apart.

Active control arm
Women in the active control arm will receive either the standard IV (Zuspan) regimen consisting of IV injection of 4 g over 10-15 minutes as a loading dose, followed by a maintenance IV infusion of 1 g per hour for 24 hours (total dose 28g); or standard IM (Pritchard) regimen consisting of IV injection of 4 g over 10-15 minutes and IM injection of 10g as a loading dose, followed by a maintenance IM injection of 5 g every 4 hours for 24 hours (total dose 39g).

Participants will be randomly assigned to either experimental or standard arms (allocation ratio of 1:1) as per a computer-generated randomization sequence in permuted blocks. All sites will receive identical treatment packs; each pack will contain the required number of magnesium sulfate ampoules for the simplified or standard regimen according to the randomization sequence. The packs will be assembled consecutively in special dispensers with slots at the lower end where treatment packs can be removed sequentially. The treatment packs will be used in the order in which they are removed through the slot in the dispenser to maintain the randomization sequence. The assignment schedule will be stored at the WHO headquarters.

After signing the informed consent, trained study staff will randomize a woman by taking the next numbered treatment pack from the dispenser. Women will be randomized to receive either the simplified IM regimen of 10g IM administered 12 hourly x 2 doses or either standard Zuspan

or Pritchard regimen, depending on the designated treatment protocol in the participating hospitals. Study participants and personnel will not be blinded to the group allocation due to the nature of study interventions.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Magnesium sulfate 50% (5 g/10 ml)

Primary outcome(s)
Maternal eclamptic seizure: occurrence of first onset of convulsions in a woman with features of pre-eclampsia that is unrelated to other neurological conditions; as documented on a participants trial chart or medical records from the time of randomization until day 7 after birth, hospital discharge, transfer to higher-level/another facility, withdrawal from study, or maternal death; whichever is first.

Key secondary outcome(s))
1. Composite endpoint describing events related to maternal toxicity and consisting of one or more of the following – absent/reduced tendon reflexes, respiratory depression, use of calcium gluconate to counteract perceived/confirmed maternal toxicity, or stopping/reduced magnesium sulfate treatment in the event of perceived/confirmed maternal toxicity: the occurrence of any of the above events related to maternal toxicity, individually documented on the participant's STEPMag chart- which documents hourly assessments for these events.
1.1 Patella reflexes as assessed by the obstetric care provider during magnesium sulfate treatment; as documented on a scale from 0 to +4; where 0 is absent reflexes, +2 is normal, and + 4 is a sustained response. Tendon reflexes are assessed from randomization until 24 hours after start of treatment and recorded in the participant STEP-Mag chart.
1.2 Respiratory depression, defined as a respiratory rate of less than 16 respirations/minute as assessed by the obstetric care provider during magnesium sulfate treatment and recorded in the participant STEP-Mag chart.
1.3 Use of calcium gluconate, defined as the use of calcium gluconate given at any time during treatment to combat perceived or confirmed magnesium sulfate toxicity and recorded in the participant STEP-Mag chart.
1.4 Stopping/reduced magnesium sulfate treatment due to perceived/confirmed magnesium toxicity; as documented in the participant STEPMag chart as the rationale for the obstetric provider to lower (e.g., halving) the dose of magnesium sulfate treatment regimen, as defined in the protocol.
2. Maternal death (all-cause and cause-specific): the death of a woman and the underlying cause, measured using a review of patient notes for events up to day 7 after birth, hospital discharge, transfer to higher level of care, maternal death, or withdrawal from the study; whichever is first.
3. Death of baby before hospital discharge (stillbirth, perinatal death or neonatal death, for women enrolled before giving birth):
3.1. Stillbirth: defined as death of a fetus after documented evidence of fetal heart beats prior to randomization and showing no signs of life at time of birth. This outcome is documented at the time of delivery. In the case of participants enrolled with an intrauterine fetal demise prior to randomization, defined as absence of fetal heart beats, as confirmed by the obstetric provider and documented on the participant's baseline information sheet.

3.2. Perinatal death: This is defined as the occurrence of stillbirth, stillbirth or neonatal death, or neonatal death following randomization in a woman enrolled prior to birth, measured using a review of patient notes from admission to day 7 after birth, hospital discharge, transfer to higher level of care, maternal death, or withdrawal from the study; whichever is first.
3.3. Neonatal death: This is defined as death of a live birth before the completion of 168 hours (7 days) after birth; as measured using a review of patient notes from admission to day 7 after birth, hospital discharge, transfer to higher level of care, maternal death, or withdrawal from the study; whichever is first.
4. Indicators of severe maternal morbidity (respiratory arrest, cardiac arrest, coagulopathy, renal failure, liver failure, pulmonary oedema, and stroke): the occurrence of any of the above severe maternal morbidity events, individually measured using a review of the participant STEPMag chart and patient notes from admission until day 7 after birth, hospital discharge, transfer to higher level of care, maternal death, or withdrawal from the study; whichever is first.
4.1. Respiratory arrest: woman not breathing or not able to breath
4.2. Pulmonary oedema: liquid accumulation in the tissues and airspaces of the lungs, diagnosed as based upon clinical auscultation or on chest X-ray
4.3. Cardiac arrest: no evidence of heart function or in setting of arrhythmia such as ventricular fibrillation
4.4. Renal failure: loss of kidney functions as a result of ischaemic injury, typically due to acute tubular necrosis in the context of pre-eclampsia
4.5. Liver failure: evidence of liver dysfunction due to severe spontaneous bleeding into the liver with haemorrhagic liver cell necrosis and rupture, haematoma, or infarction, hepatic encephalopathy or coma
4.6. Disseminated intravascular coagulopathy: This is an acquired syndrome characterized by the intravascular activation of coagulation with loss of localization arising from different causes. In pregnancy, diagnosis is based upon platelet count, fibrinogen and differences in prothrombin time.
4.7. Stroke: a serious life-threatening medical condition that happens when the blood supply to part of the brain is cut off. It could be ischaemic due to decreased blood flow to areas of the brain, or haemorrhagic due to bleeding into the brain by the rupture of a blood vessel. Signs and symptoms of a stroke may include an inability to move or feel on one side of the body, problems understanding or speaking, dizziness, or loss of vision to one side.
5. Maternal intensive care unit (ICU) admission: admission of a woman for intensive care in the hospital, measured using a review of patient notes from admission to day 7 after birth, hospital discharge, transfer to higher level of care, maternal death, or withdrawal from the study; whichever is first.
6. Recurrence of seizures (for women with eclampsia): the occurrence of the second or further episodes of generalized tonic clonic convulsion, measured using a review of patient notes from admission to day 7 after birth, or hospital discharge, transfer to higher level of care, maternal death, or withdrawal from the study; whichever is first.
7. Maternal side effects of magnesium sulfate (nausea or vomiting, flushing of the skin, drowsiness, confusion, muscle weakness, problem at injection site – pain, injection abscess with IM or IV administration): the occurrence of any of the above side effects, individually measured using a review of the participant STEPMag chart and patient notes.
7.1. Nausea or vomiting, flushing of the skin, drowsiness, confusion, muscle weakness recorded hourly for the 24 hours (on magnesium treatment)
7.2. problem at injection site – pain, injection abscess with IM or IV administration), as recorded hourly for the 24 hours (on magnesium treatment) or until transfer to higher level of care, death, withdrawal from the study, or 7 days after birth if the woman remains admitted; whichever is first.
8. Mode of birth (caesarean section or vaginal birth): the final mode of birth for a woman who was randomized prior to giving birth, measured using a review of the patient notes at the time

of birth.
9. Induction of labour: the artificial initiation of labour in a woman who was randomized prior to giving birth, measured using a review of the patient notes from the time of birth.
10. Augmentation of labour: the artificial stimulation of labour in a woman who was randomized prior to giving birth, measured using a review of the patient notes from the time of birth.
11. Abruptio placenta: the occurrence of premature separation of the placenta in a woman who was randomized prior to giving birth, measured using a review of the patient notes from the time of birth.
12. Postpartum haemorrhage: the occurrence of postpartum blood loss estimated at ≥ 500 mL following a vaginal birth or ≥ 1000 mL following a caesarean birth within 24 hours after birth (i.e. primary postpartum haemorrhage) in a woman who was randomized prior to giving birth, measured using a review of the patient notes at 24 hours after birth.
13. Treatment with additional uterotonics for postpartum haemorrhage: the use of additional uterotonic(s) for therapeutic treatment of primary postpartum haemorrhage (in addition to any prophylactic uterotonics) in a woman who was randomized prior to giving birth, measured using a review of the patient notes from 24 hours after birth.
14. Blood transfusion: the use of any blood or blood products (i.e., no minimum volume) in a woman who was randomized prior to giving birth, measured using a review of the patient notes from admission to day 7 after birth, hospital discharge, transfer to higher level of care, maternal death, or withdrawal from the study; whichever is first.
15. Retained placenta: as placenta or membranes that have not been expelled from the uterus during the third stage of labour and up to 30 minutes following childbirth in a woman who was randomized prior to giving birth, measured using a review of the patient notes up to 24 hours after birth.
16. Indicators of severe neonatal morbidity (Apgar <7 at 5 minutes, need for intubation at birth, ventilation, seizures, admission to neonatal intensive care or special care unit): the occurrence of any of the above severe neonatal morbidity events in a woman who was randomized prior to giving birth.
16.1. Apgar < 7 at 5 minutes: Apgar score of the baby at 5 minutes of life lower than 7 out of 10; individually measured using a review of patient notes from the time of birth.
16.2. Need for intubation at birth: Intubation received at time of birth. This outcome relates specifically to intubation at the time of birth; individually measured using a review of patient notes from the time of birth.
16.3. Ventilation: Any ventilation received by the infant from time of birth (mechanical ventilation, use of supplemental oxygen, or CPAP); individually measured using a review of patient notes from the time of birth.
16.4. Neonatal seizures: Any neonatal convulsion experienced between time of birth and until day 7 after birth, maternal discharge, transfer to higher level care, death, or withdrawal from the study (whichever is earliest). A convulsion can be any of the following signs, criteria are listed below:
16.4.1 Generalized convulsion (repetitive jerking movements of limbs or face; continuous extension or flexion of arms and legs, either synchronous or asynchronous: apnoea (spontaneous cessation of breathing for more than 20 seconds); or the baby may appear unconscious or awake but unresponsive.
16.4.2 Subtle convulsion (Repetitive blinking, eye deviation, or staring; repetitive movements of mouth or tongue; purposeless movement of the limbs, as if bicycling or swimming; or apnea: the baby may be conscious .
17. Gestational age at birth: the gestational age (in weeks ± days) at which the baby of a woman randomized was born, measured using a review of the patient notes at the time of birth (for women randomized prior to birth).
18. Birthweight: the birthweight of the baby (in grams) of a woman randomized, measured using a review of the patient notes at the time of birth for women randomized prior to birth)

19. Small-for-gestational age: an infant with birth weight less than 10th centile for the gestational age, based on obstetric assessment of gestational age, birthweight, and the neonatal growth chart (length vs weight), measured using a review of patient notes at the time of birth for a woman randomized prior to birth.
20. Maternal satisfaction: satisfaction of a woman with magnesium sulfate regimen received, measured using a modified treatment satisfaction for medication questionnaire at the time of discharge.

Completion date
15/12/2028

Eligibility

Key inclusion criteria
1. Be admitted with a diagnosis of pre-eclampsia and with clinical or laboratory indication(s) for magnesium sulfate treatment, as defined by any of the following: two readings of systolic blood pressure ≥160 mmHg, or diastolic blood pressure ≥110 mmHg along with ≥2+ proteinuria on urine dipstick; or the presence of symptoms, signs or laboratory findings suggestive of severe disease such as headache, visual disturbances, upper abdominal pain, pulmonary oedema, nausea and vomiting, hyperreflexia or clonus, elevated liver enzymes, raised serum creatinine, or thrombocytopenia. Women with HELLP syndrome, a severe form of pre-eclampsia characterized by Haemolysis, Elevated Liver enzymes, and Low Platelets (<100 cells/mcl) will be included if there is no clinical contraindication to IM injection.
2. Have not yet given birth but birth is planned or expected within the next 24 hours, or have given birth within the last 24 hours.
3. Provide written informed consent before any trial-related procedures are carried out.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Unable or unwilling to give informed consent (because the woman is too distressed or not capable to understand, confirm and give informed consent due to emergency or health condition, or does not wish to be randomized for whatever reason).
2. Are non-emancipated minors (as per local regulations) without a guardian.
3. History of hypersensitivity to magnesium sulfate.
4. Serious cardiovascular disorders (WHO classification III or IV or acute heart failure).
5. Serious hepatic (encephalopathy or coma) or renal disease.

6. History of epilepsy.
7. Myasthenia gravis or any muscular dystrophies.
8. Coagulopathy.
9. Have previously received magnesium sulfate for eclampsia prevention in the current pregnancy.
10. Planned to receive magnesium sulfate regimen other than the regimens specified for the trial on account of other medical indication(s) (e.g. fetal neuroprotection).
11. Known oliguria (<400mL urine in 24 hours) at the time of admission.

Date of first enrolment
24/11/2022

Date of final enrolment
30/01/2028

Locations

Countries of recruitment
Egypt

India

Kenya

Malawi

Nigeria

Rwanda

South Africa

Uganda

Study participating centre
Gadag Institute of Medical Services
Karnataka
India
582103

Study participating centre
SCB Medical College, Cuttack
Cuttack
India
753007

Study participating centre
JJM Medical College, Davanagere
Davanagere
India
577004

Study participating centre
Raichur Institute of Medical Sciences (RIMS)
Karnataka
India
584102

Study participating centre
Mama Lucy Hospital
Nairobi
Kenya
000

Study participating centre
Naivasha Level 5 Hospital
Naivasha
Kenya
000

Study participating centre
Mbagathi County Hospital
Nairobi
Kenya
000

Study participating centre
Queen Elizabeth Central Hospital
Blantyre
Malawi
000

Study participating centre

Zomba Central Hospital
Zomba
Malawi
000

Study participating centre
Bwaila District Hospital
Lilongwe
Malawi
000

Study participating centre
Aminu Kano Teaching Hospital
Kano
Nigeria
700101

Study participating centre
Murtala Muhammad Specialist Hospital
Kano City
Nigeria
700224

Study participating centre
Chris Hani Baragwanath Academic Hospital
Johannesburg
South Africa
1864

Study participating centre
Tembisa Provincial Tertiary Hospital
Tembisa
South Africa
1632

Study participating centre

Kawempe
Kampala
Uganda
000

Study participating centre
MKCG Medical College and Hospital
Odisha
India

Study participating centre
Gandhi Medical Center
Telangana
India

Study participating centre
Koppal Institute of Medical Sciences
Karnataka
India

Study participating centre
Katali Hospital
Kitali
Kenya

Study participating centre
Muhammadu Wase Teaching Hospital
Kano
Nigeria

Study participating centre
UDUTH Sokoto
Sokoto
Nigeria

Study participating centre

Kibagabaga
Kigali
Rwanda

Study participating centre
Ruhengeri
Musanze
Rwanda

Sponsor information

Organisation
World Health Organization

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp and Dohme

Alternative Name(s)
MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)

Results and Publications

Individual participant data (IPD) sharing plan

This project will generate an anonymized research data set, with de-identified information of characteristics and outcomes from all women and babies participating in the trial. Once the trial is completed and primary results published, this data set will be subject to the WHO data sharing policy. WHO will ensure long-term storage and sharing of anonymized multi-site data sets in an appropriate public repository for their further use.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			29/06/2022	No	Yes