

Magnesium sulphate in Tetanus

Submission date 27/08/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/03/2013	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Catherine Thwaites

Contact details

Oxford University Clinical Research Unit
Hospital for Tropical Diseases
190 Ben Ham Tu
Ho Chi Minh City
Viet Nam
Q5

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

066689/z

Study information

Scientific Title

Acronym

Magnesium in Tetanus

Study objectives

Magnesium sulphate is better than conventional treatment in controlling spasms and autonomic instability in the management of severe tetanus.

Ethics approval required

Old ethics approval format

Ethics approval(s)

OXTREC (Oxford University Tropical Research Ethical Committee) approval gained for study in March 2002 (reference number: 003-02) and Hospital for Tropical Diseases Scientific and Ethical Committee, Ho Chi Minh City, Viet Nam, approved of study in March 2002.

Study design

Double blind, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Tetanus

Interventions

Group one - intervention group: Magnesium Sulphate intravenous (iv) infusion 0.5 - 2 g/hr.
Group two - control group: Conventional treatment of intravenous diazepam (bolus 5 - 10 mg) or midazolam (infusion 1 - 10 mg/hr), but if spasms were not controlled intravenous infusions of pipercuronium were given. Autonomic disturbance was treated with verapamil, morphine or digoxin.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Magnesium sulphate, diazepam and midazolam

Primary outcome measure

Requirement for mechanical ventilation primary outcome

Secondary outcome measures

1. Requirement for benzodiazepines, pipecuronium, morphine and verapamil (mg/kg)
2. Hourly Systolic Blood Pressure (SBP) and Heart Rate (HR) recording and mean seven day maximum SBP, HR and daily variation in SBP
3. In hospital mortality (including patients taken home to die)
4. Length of Intensive Care Unit (ICU) stay, total hospital stay and total cost of hospital stay
5. Requirement for ventilation during hospital stay
6. Daily 8 am serum Creatinine Kinase (CK) measurement
7. Urinary epinephrine and norepinephrine, measured from a 24 hour collection on day two of the study

Overall study start date

01/05/2002

Completion date

01/05/2005

Eligibility

Key inclusion criteria

1. Adults with Ablett classification of tetanus severity grade three or four
2. Patient over 15 years with diagnosed tetanus
3. Tracheostomy more than six hours and not yet ventilated

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

180

Key exclusion criteria

1. Urine output less than 1 ml/kg/hr
2. Electrocardiogram (ECG) evidence of conduction abnormalities/ischaemia
3. Serum creatinine more than 1.5 mg%

Date of first enrolment

01/05/2002

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

Viet Nam

Study participating centre

Oxford University Clinical Research Unit

Ho Chi Minh City

Viet Nam

Q5

Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

University Offices

Wellington Square

Oxford

England

United Kingdom

OX1 2JD

Sponsor type

University/education

Website

<http://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 066689)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	21/10/2006		Yes	No