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Magnesium sulphate in Tetanus

Submission date	Recruitment status	[_] Prospectively registered
27/08/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/03/2013	Infections and Infestations	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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 hypothesis
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

Condition
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 pipecuronium were given. Autonomic distrubance 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

Overall study end date
01/05/2005

Eligibility

Participant 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

Participant 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%

Recruitment start date
01/05/2002

Recruitment end date

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