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Double blind placebo controlled trial of steroids in Bacterial Meningitis

Submission date	Recruitment status	[ ] Prospectively registered
22/07/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/10/2022	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
061330

Study information

Scientific Title
Double blind placebo controlled trial of steroids in Bacterial Meningitis

Acronym
BM Study

Study objectives
To investigate the effects of dexamethazone on the course and outcome of Bacterial Meningitis (BM) in adults in Viet Nam.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bacterial meningitis

Interventions
Double blind randomised controlled trial. The intervention will be dexamethasone.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dexamethazone

Primary outcome(s)
Mortality

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/01/2000

Eligibility

Key inclusion criteria

1. The treating physician believes the diagnosis to be BM
2. History less than ten days (unless still Serebrospinal Fluid [CSF] evidence of bacteria)
3. CSF white cell count more than 50 with more than 50% neutrophils
4. CSF glucose less than 50% of blood glucose

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Chest X-Ray (CXR) shows evidence of possible Tuberculosis (TB)
2. History is longer than ten days
3. History of hypersensitivity to beta-lactam antibiotics
4. Known severe liver or renal impairment
5. Patients in whom the physician believes corticosteroids are contraindicated e.g. uncontrolled diabetes, gastro-intestinal bleeding etc.
6. Pre-existing severe neurological disability
7. Pregnancy within the first trimester

Date of first enrolment
01/11/1996

Date of final enrolment
01/01/2000

Locations

Countries of recruitment
Viet Nam

Study participating centre
Hospital for Tropical Diseases
Ho Chi Minh City
Viet Nam
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Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 061330)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		21/10/2004		Yes	No
Results article		13/12/2007		Yes	No