

Double blind placebo controlled trial of steroids in Bacterial Meningitis

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2022	Condition category Nervous System Diseases	<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

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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 Cerebrospinal 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