Dexamethasone adjuvant therapy and intramuscular ceftriaxone in bacterial meningitis amongst adults in an area of high human immunodeficiency virus (HIV) prevalence in Blantyre, Malawi

Submission date	Recruitment status No longer recruiting	Prospectively registered		
16/08/2005		☐ Protocol		
Registration date 07/09/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited 18/12/2007	Condition category Infections and Infestations	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number P.98/99/30R

Study information

Scientific Title

Acronym

SAM Trial (Steroids in Adult Meningitis)

Study objectives

- 1. Dexamethasone, by limiting the host inflammatory response in bacterial meningitis, will reduce mortality and morbidity
- 2. Ceftriaxone is as effective given intramuscularly (IM) as it is when given intravenously (IV) and may therefore be used in rural areas where IV therapy is unavailable

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

Dexamethasone 16 mg twice daily for 4 days versus placebo. Ceftriaxone 2 mg twice daily for ten days given either IV or IM.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dexamethasone, ceftriaxione

Primary outcome(s)

Mortality at 40 days

Key secondary outcome(s))

- 1. Death or disability at 40 days
- 2. Clinically apparent hearing loss at 40 days
- 3. Death at six months

Completion date

31/01/2005

Eligibility

Key inclusion criteria

All adults admitted to the Queen Elizabeth Central Hospital, Blantyre with a preliminary diagnosis of bacterial meningitis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Age less than 16 years
- 2. Steroids received within the 24 hours preceeding admission

Date of first enrolment

15/05/2002

Date of final enrolment

31/01/2005

Locations

Countries of recruitment

United Kingdom

England

Malawi

Study participating centre 27 Oatlands Rd

Oxford United Kingdom OX2 0EU

Sponsor information

Organisation

College of Medicine Research Committee (Malawi)

ROR

https://ror.org/04vtx5s55

Funder(s)

Funder type

Charity

Funder Name

Meningitis Research Foundation (UK)

Alternative Name(s)

meningitisresearch, meningitisRF, Meningitis Research Foundation: Meningitis and septicaemia, Meningitis Research Foundation (UK), M R F, MRF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	13/12/2007		Yes	No