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 16/08/2005	Recruitment status No longer recruiting	 Prospectively registered 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers P.98/99/30R

Study information

Scientific Title

Acronym

SAM Trial (Steroids in Adult Meningitis)

Study objectives

 Dexamethasone, by limiting the host inflammatory response in bacterial meningitis, will reduce mortality and morbidity
 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

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 measure Mortality at 40 days

Secondary outcome measures

Death or disability at 40 days
 Clinically apparent hearing loss at 40 days
 Death at six months

Overall study start date 15/05/2002

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

Age group Adult

Sex Both

Target number of participants 420

Key exclusion criteria

Age less than 16 years
 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 England

Malawi

United Kingdom

Study participating centre 27 Oatlands Rd Oxford United Kingdom OX2 0EU

Sponsor information

Organisation College of Medicine Research Committee (Malawi)

Sponsor details

Private Bag 360 Chichiri Blantyre Malawi BT3

Sponsor type University/education

ROR https://ror.org/04vtx5s55

Funder(s)

Funder type Charity

Funder Name Meningitis Research Foundation (UK)

Alternative Name(s) MRF **Funding Body Type** Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

Location United Kingdom

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?
<u>Results article</u>	Results	13/12/2007		Yes	Νο