ISRCTN31371499 https://doi.org/10.1186/ISRCTN31371499

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

Registration date
07/09/2005

Overall study status
Completed

Last Edited
18/12/2007

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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

Primary study design
Interventional

Study design
Randomised controlled trial

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