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

Registration date
07/09/2005

Last Edited
18/12/2007

Recruitment status
No longer recruiting

Overall study status
Completed

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

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
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

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
1. Death or disability at 40 days
2. Clinically apparent hearing loss at 40 days
3. 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
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
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?
Results article	Results	13/12/2007		Yes	No