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Randomised controlled trial of glycerol adjuvant therapy in adult bacterial meningitis in Malawi

Submission date 29/11/2005	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Stopped	
Last Edited 04/07/2011	**Condition category** Infections and Infestations	

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
N/A

Study information

Scientific Title

Acronym
GLAM

Study objectives
Glycerol adjuvant therapy improves outcome in adult patients with bacterial meningitis

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. College of Medicine Research and Ethics Committee (COMREC), University of Malawi, Malawi, approved in January 2006
2. Liverpool School of Tropical Medicine, UK, approved in February 2006 (ref: 05/64A)

Study design
Double-blind placebo-controlled randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Meningitis

Interventions
This trial was stopped in August 2008 following a planned (unblinded) interim analysis due to safety issues. In total 265 patients were randomised.

Phase I - Forty five patients will be recruited for assessment of glycerol tolerability. Fifteen patients each will receive glycerol at a dose of 25 ml twice a day (bd), 25 ml four times a day (qds) or 50 ml qds for four days.
Phase II - Patients will be randomised by computer generated permuted blocks to receive glycerol adjuvant therapy at the highest tolerated dose, or equivalent volume of 50% dextrose, for four days. All patients will receive bacterial meningitis treatment, in Malawi the standard guidelines are with parenteral penicillin and chloramphenicol for a minimum of 10 days.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Glycerol

Primary outcome measure
Phase I: Tolerability of glycerol adjuvant therapy and serious adverse events
Phase II: Death by 1 month

Secondary outcome measures
1. Physician decision to alter treatment based on the occurrence of complications
2. Death or residual neurological deficit (Glasgow Outcome Score and hearing loss) at discharge, and one month after completing antibiotic therapy
3. Time to death, time to discharge
4. Effect of glycerol on change in CSF pressure. We will also aim to perform a sub-study on a limited set of patients to gain data on CSF penetration of glycerol.

Overall study start date
05/01/2006

Completion date
30/12/2009

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Patients >=16 years old admitted with headache, fever and neck stiffness AND cerebrospinal fluid (CSF) findings suggestive of bacterial meningitis, defined as: cloudy CSF in a patient requiring immediate treatment or greater than 100 white cells/ml in the CSF with predominant neutrophils or gram-stain showing bacteria
2. Informed consent given (or in the case of unconscious patients, their guardian on their behalf), patient willing to follow study protocol

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Pregnant females
2. Type II diabetics
3. Patients with heart failure
4. Patients whose CSF results indicate infection by cryptococcus or mycobacteria

Date of first enrolment
05/01/2006

Date of final enrolment
30/12/2009

Locations

Countries of recruitment
Malawi

Study participating centre
Dept of Medicine
Blantyre
Malawi
BT3

Sponsor information

Organisation
University of Malawi, College of Medicine (Malawi)

Sponsor details
EE Zijlstra
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Sponsor type
University/education

Website
http://www.medcol.mw/

ROR

https://ror.org/04vtx5s55

Funder(s)

Funder type
Charity

Funder Name
Meningitis Research Foundation (United Kingdom)

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	01/04/2011		Yes	No