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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

## 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)

## Primary study design
Interventional

## Study design
Double-blind placebo-controlled randomised controlled trial

## Study type(s)
Treatment

## 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(s)
Phase I: Tolerability of glycerol adjuvant therapy and serious adverse events
Phase II: Death by 1 month

## Key secondary outcome(s)

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.

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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)

**ROR**
https://ror.org/04vtx5s55

# Funder(s)

**Funder type**
Charity

**Funder Name**
Meningitis Research Foundation (United Kingdom)

**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 | 01/04/2011 | | Yes | No |