

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

Submission date 29/11/2005	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
Registration date 20/12/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 04/07/2011	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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)

Study design

Double-blind placebo-controlled randomised controlled trial

Primary study design

Interventional

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