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Evaluating the potential role of oral activated charcoal as an adjunct treatment for severe bacterial infections and severe malaria - a preliminary safety study

Submission date
17/05/2006

Recruitment status
No longer recruiting

Registration date
08/08/2006

Overall study status
Completed

Last Edited
27/04/2010

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
SCC 1025

Study information

Scientific Title

Study objectives
In mice, oral administration of activated charcoal improves survival in Lipopolysaccharide (LPS)-induced endotoxemia, during sepsis and cerebral malaria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by Gambian government/Medical Research Council Laboratories Joint Ethics Committee on 23 December 2005.

Study design
Open labelled randomised, non-blinded controlled population based pharmacokinetic study (phase I study)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asymptomatic parasitaemia for Plasmodium falciparum

Interventions
Co-administration of oral activated charcoal and intravenous (i.v.) artesunate to study participants randomised into three groups as follows:
Group one (control): i.v. artesunate without adjuvant treatment, plus 350 mls of water given orally with each i.v. dose
Group two: i.v. artesunate with simultaneous administration of oral activated charcoal (50 g) with each dose of artesunate
Group three: i.v. artesunate followed by oral activated charcoal (50 g) given one hour after each dose of artesunate.

All subjects will receive 2.4 mg/kg of i.v. artesunate at zero, 12 and 24 hours. To avoid recrudescence, the study participants will receive a full course of Co-artem (four tablets twice daily for three days) used as a follow-on therapy starting 72 hours after the first dose of i.v. artesunate.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Activated charcoal, artesunate

Primary outcome(s)
Impact of oral activated charcoal on the pharmacokinetics of parenteral artesunate.

Key secondary outcome(s))
Reduced parasite clearance of i.v. artesunate

Completion date
29/10/2006

Eligibility

Key inclusion criteria
Healthy African adults aged 15-45 years with asymptomatic parasitaemia confirmed on a thick blood film.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Haemoglobin less than 11 g/dl
2. Detectable levels of chloroquine in the urine
3. Mixed infections
4. Concurrent participation in another study
5. Pregnant or breastfeeding

Date of first enrolment
29/05/2006

Date of final enrolment
29/10/2006

Locations

Countries of recruitment
Gambia

Study participating centre
Malaria Programme
Fajara

Gambia
P.O.Box 273

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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				

Results article	15/04/2010	Yes	No