ISRCTN64793756 https://doi.org/10.1186/ISRCTN64793756

# 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### 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
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 measure
Impact of oral activated charcoal on the pharmacokinetics of parenteral artesunate.

### Secondary outcome measures
Reduced parasite clearance of i.v. artesunate

### Overall study start date
29/05/2006

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
90

### 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**
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P.O.Box 273

## Sponsor information

**Organisation**
Medical Research Council (MRC) (UK)

**Sponsor details**
20 Park Crescent
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+44 (0) 2076 365422
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**Sponsor type**
Government

**Website**
http://www.mrc.ac.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

**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 | 15/04/2010 | | Yes | No |