

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	☐ Prospectively registered
Registration date 08/08/2006	Overall study status Completed	☐ Protocol
Last Edited 27/04/2010	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ 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.

Primary study design

Interventional

Study design

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

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, Medical Research Committee and Advisory 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?
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[Results article](#)

results

15/04/2010

Yes

No