

Antibiotics to prevent preterm birth

Submission date 14/12/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 18/12/2007	Overall study status Completed	☐ Protocol
Last Edited 21/03/2013	Condition category Pregnancy and Childbirth	☐ 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

065810/Z/01/Z

Study information

Scientific Title

A randomised, community-based trial of Azithromycin for the Prevention of Pre-term Labour in Malawi

Acronym

APPLe

Study objectives

That routine antibiotic prophylaxis in a pregnant population with high burdens of infection, and high incidence of preterm birth, would reduce the incidence of prematurity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

College Of Medicine Research Ethics Committee (COMREC), Blantyre (Malawi) approved in November 2003

Primary study design

Interventional

Study design

Four centre placebo-controlled, randomised trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Preterm birth

Interventions

Azithromycin 1 g orally or placebo at 16 - 24 weeks and 28 - 32 weeks. For main trial, follow-up was to 6 weeks after birth. Children have been followed up to 18 months of age.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Azithromycin

Primary outcome(s)

Preterm birth (less than 37 weeks gestation).

Key secondary outcome(s)

1. Mean gestational age at birth
2. Perinatal mortality
3. Birthweight
4. Malarial parasites at 28 - 32 weeks
5. Haemoglobin at 28 - 32 weeks

Completion date

31/07/2007

Eligibility

Key inclusion criteria

1. Pregnant women less than 24 weeks gestational age by ultrasound at recruitment
2. No age restriction, apart from age being compatible with pregnancy
3. Intention to remain within the district throughout pregnancy
4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/02/2004

Date of final enrolment

31/07/2007

Locations

Countries of recruitment

United Kingdom

England

Malawi

Study participating centre

School of Reproductive and Developmental Medicine

Liverpool

United Kingdom

L8 7SS

Sponsor information

Organisation

University of Liverpool (UK)

ROR

<https://ror.org/04xs57h96>

Funder(s)**Funder type**

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 065810)

Funder Name

Pfizer Inc. (USA) - supplied drug and placebo

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 article	results	01/12/2009		Yes	No