

# Antibiotics to prevent preterm birth

<b>Submission date</b> 14/12/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/12/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/03/2013	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof Jim Neilson

### Contact details

School of Reproductive and Developmental Medicine  
University of Liverpool  
1st floor, Liverpool Women's Hospital  
Liverpool  
United Kingdom  
L8 7SS  
+44 (0)151 702 4100  
[jneilson@liv.ac.uk](mailto:jneilson@liv.ac.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Study design**

Four centre placebo-controlled, randomised trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****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 measure**

Preterm birth (less than 37 weeks gestation).

**Secondary outcome measures**

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

**Overall study start date**

01/02/2004

**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

**Age group**

Adult

**Sex**

Female

**Target number of participants**

2300

**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**

England

Malawi

United Kingdom

**Study participating centre**  
**School of Reproductive and Developmental Medicine**  
Liverpool  
United Kingdom  
L8 7SS

## **Sponsor information**

**Organisation**  
University of Liverpool (UK)

**Sponsor details**  
Brownlow Hill  
Liverpool  
England  
United Kingdom  
L69 3BX  
jdowson@liv.ac.uk

**Sponsor type**  
University/education

**Website**  
<http://www.liv.ac.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

**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?
<a href="#">Results article</a>	results	01/12/2009		Yes	No