ISRCTN84023116 https://doi.org/10.1186/ISRCTN84023116

Antibiotics to prevent preterm birth

Submission date
14/12/2007

Recruitment status
No longer recruiting

Registration date
18/12/2007

Overall study status
Completed

Last Edited
21/03/2013

Condition category
Pregnancy and Childbirth

[ ] 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

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

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

Study design
Four centre placebo-controlled, randomised trial

Primary study design
Interventional

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