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Overview of the Role of Antibiotics in Curtailing Labour and Early delivery

Submission date	Recruitment status	[_] Prospectively registered
25/10/2000	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2000	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/07/2018	Pregnancy and Childbirth	

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
G9226450

Study information

Scientific Title
Overview of the Role of Antibiotics in Curtailing Labour and Early delivery (ORACLE)

Acronym
ORACLE

Study objectives
The ORACLE trial is designed to test the hypothesis that treatment of women with idiopathic preterm labour or preterm rupture of the membranes (PROM) with broad spectrum antibiotics reduces neonatal mortality and morbidity due to preterm birth

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 18/07/2007: Approved by West Midlands Multicentre Research Ethics Committee.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Obstetrics and gynaecology

Interventions
Broad spectrum antibiotics/placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Neonatal death, Chronic lung disease, Major cerebral pathology

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1994

Completion date
31/03/2009

Eligibility

Key inclusion criteria
Pregnant women less than 37 weeks gestation either in preterm labour or with premature rupture of membranes (PROM)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
10000

Key exclusion criteria
Need for immediate delivery, contraindications for antibiotics

Date of first enrolment
01/07/1994

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Obstetrics & Gynaecology
Leicester
United Kingdom
LE2 7LX

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
London
United Kingdom
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clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

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

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (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	ORACLE I results	31/03/2001		Yes	No
Results article	ORACLE II results	31/03/2001		Yes	No
Results article	ORACLE trials results	01/06/2005		Yes	No
Results article	ORACLE I trial results	11/10/2008		Yes	No
Results article	ORACLE II trial results	11/10/2008		Yes	No