

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

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 05/07/2018	Condition category 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
Dr Robin Youngs

Contact details
Department of Obstetrics & Gynaecology
Clinical Sciences Building
Leicester Royal Infirmary
Gloucester
United Kingdom
GL1 3NN
+441452394205
abc@123.com

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
W1B 1AL
+44 (0)20 7636 5422
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