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Randomised double blind placebo controlled trial of antimicrobial treatment in pregnant women at risk of preterm labour

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/05/2016	Pregnancy and Childbirth	[ ] Record updated in last year

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

N0263022099

Study information

Scientific Title
Randomised double blind placebo controlled trial of antimicrobial treatment in pregnant women at risk of preterm labour

Study objectives
Does treatment of fetal fibronectin positive pregnant women with an antimicrobial drug reduce the incidence of preterm labour and delivery?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Preterm labour

Interventions
Randomised controlled trial:
A. Antibiotic
B. Placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

Preterm labour and delivery. Delivery after 37 weeks gestation.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1997

Completion date
01/07/2003

Eligibility

Key inclusion criteria
75 Patients from Obstetrics/Midwifery.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
75

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/07/1997

Date of final enrolment
01/07/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Department of Obstetrics and Gynaecology
London
United Kingdom
WC1E 6HX

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospitals NHS Trust (UK)

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