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

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

Protocol serial number
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

Study type(s)
Prevention

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(s)
Preterm labour and delivery. Delivery after 37 weeks gestation.

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/07/2003

Eligibility

Key inclusion criteria
75 Patients from Obstetrics/Midwifery.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

Study participating centre
Department of Obstetrics and Gynaecology
London
United Kingdom
WC1E 6HX

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University College London Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration