

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/05/2016	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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