

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
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 25/05/2016	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr GCL Lachelin

Contact details

Department of Obstetrics and Gynaecology
Royal Free and University College Medical School
86-96 Chenies Mews
London
United Kingdom
WC1E 6HX
+44 (0)20 7209 6054
gillian.lachelin@ucl.ac.uk

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

Primary study design

Interventional

Study design

Randomised placebo controlled parallel group trial

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