Randomised controlled trial of prophylactic antibiotics at the time of oocyte retrieval and their impact on incidence of bacterial contamination of the catheter used for embryo transfer, embryo implantation and pregnancy rates.

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
30/09/2005				
Registration date	Overall study status Completed	Statistical analysis plan		
30/09/2005		[X] Results		
Last Edited	Condition category	[] Individual participant data		
01/07/2010	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Yakoub A Khalaf

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0013146096

Study information

Scientific Title

Study objectives

Impact of prophylactic antibiotics at the time of oocyte retrieval on incidence of bacterial contamination of the catheter used for embryo transfer, embryo implantation and pregnancy rates.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 25/06/10:

Received from South East London REC 1 (formerly Guy's Research Ethics Committee)

Study design

Randomised controlled 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

Embryo implantation

Interventions

Randomised controlled trial of patients into antibiotics or no treatment.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Incidence of bacterial contamination of mock catheter and embryo transfer catheter, embryo implantation and pregnancy rates.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/2004

Completion date

01/05/2004

Eligibility

Key inclusion criteria

Patients undergoing embryo transfer without any indication of pelvic infection.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

350

Key exclusion criteria

- 1. Patients allergic to penicillin
- 2. Patients previously in trial
- 3. Patients who required antibiotics at the time of egg collection

Date of first enrolment

01/03/2004

Date of final enrolment

01/05/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Guy's & St Thomas' NHS Foundation Trust
London
United Kingdom
SE1 9RT

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type

Government

Funder Name

Guy's and St. Thomas' NHS Foundation Trust (UK) - NHS R&D Support Funding

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	results	01/11/2006		Yes	No