

The effect of pharmacological agents on uterine junctional zone contractions during mock embryo transfer: a randomised double-blind study

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/03/2020	Condition category 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

N0084096582

Study information

Scientific Title

The effect of pharmacological agents on uterine junctional zone contractions during mock embryo transfer: a randomised double-blind study

Study objectives

To assess if junctional zone contractions can be reduced by pharmacological agents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double-blind study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Embryo transfer

Interventions

The patient's baseline junctional zone contractions will be established following a 5 minute scan. Video tapes taken of both the pre and post mock embryo transfer will be assessed by two researchers who will be unaware of treatment.

20 patients allocated to the nitric oxide group, 20 to the non-steroidal anti-inflammatory group, 20 control and 20 to the COX-2 inhibitor group.

Intervention Type

Drug

Phase

Not Applicable

Primary outcome measure

1. Number of contractions per unit time
2. Speed of contractions in cm/min
3. Type of contractions
4. Speed of Echovist
5. Distance traveled by Echovist

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2000

Completion date

10/12/2003

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

80

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2000

Date of final enrolment

10/12/2003

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
The Princess Royal Hospital
Hull
United Kingdom
HU8 9HE

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Research organisation

Funder Name
The North and South Bank Research and Development Consortium (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