Should the site of embryo transfer be changed according to endometrial cavity length?

Submission date 11/02/2015	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 27/02/2015	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 29/07/2015	Condition category Pregnancy and Childbirth	[] Individual participant data

Plain English summary of protocol

Background and study aims

There is a lot of debates about the best area in the endometrial cavity in which to transfer embryos. The aim of the study is to compare two areas and assess the impact on implantation and pregnancy rates.

Who can participate? Female adults going for embryo transfers at the CHA Fertility Center of Bundang CHA General Hospital

What does the study involve? Participants are randomly allocated to one of two groups: group A = embryo transfer 2cm from fundal endometrium (DFE) or group B = at the midpoint of the endometrial cavity length (ECL)

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? CHA Fertility Center of Bundang CHA General Hospital (South Korea)

When is the study starting and how long is it expected to run for? From July 2012 to December 2014.

Who is funding the study? CHA Fertility Center of Bundang CHA General Hospital (South Korea)

Who is the main contact? hwangkwon98@gmail.com

Contact information

Type(s) Scientific **Contact name** Dr hwang kwon

Contact details CHA Fertility Center of Bundang CHA General Hospital 351 Yatap-dong Bundang-gu Seongnam Korea, South 463-712

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Should the site of embryo transfer be changed according to endometrial cavity length: a prospective randomized controlled trial

Study objectives

There is a difference in implantation rates and pregnancy rates when the site of the embryo transfer is positioned 2 cms from the fundal endometrium (DFE) or at the midpoint of the endometrial cavity length (ECL).

Ethics approval required Old ethics approval format

Ethics approval(s) Institutional Review Board of Bundang CHA Hospital, 04/07/2012, ref: BD2012-095D

Study design Randomised controlled trial

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

Interventions

Group A: embryo transfer catheter tip positioned at 2 cm DFE Group B: embryo transfer catheter tip positioned at midpoint area of ECL

Intervention Type

Procedure/Surgery

Primary outcome measure

Pregnancy outcomes such as implantation rates, chemical pregnancy rates, clinical pregnancy rates, ongoing pregnancy rates.

Secondary outcome measures Ectopic pregnancy and miscarriage rates.

Overall study start date 01/06/2012

Completion date 31/12/2014

Eligibility

Key inclusion criteria All women who undergo controlled ovarian stimulation.

Participant type(s) Patient

Age group Adult

Sex Female

Target number of participants 100 in each group compared. 200 women in total.

Key exclusion criteria

1. When embryos are expected to be frozen due to ovarian hyperstimulation.

2. When embryo transfer is not performed by same physician because of absence of physician.

Date of first enrolment 01/06/2012

Date of final enrolment 18/12/2014

Locations

Countries of recruitment Korea, South

Study participating centre CHA Fertility Center of Bundang CHA General Hospital 351 Yatap-dong Bundang-gu Seongnam Gyeonggi-do Seongnam Korea, South 463-712

Sponsor information

Organisation Bundang CHA General Hospital

Sponsor details 351 Yatap-dong, Bundang-gu, Seongnam Korea, South 463-712

Sponsor type Hospital/treatment centre

Website http://bundang.chamc.co.kr/MedicalInfo/ClinicalTestBoardView.aspx? menucode=1528&no_index=136

ROR https://ror.org/04yka3j04

Funder(s)

Funder type Hospital/treatment centre

Funder Name Bundang CHA General Hospital

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date 30/08/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/07/2015		Yes	No