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Advice to have sexual intercourse around embryo transfer and its effect on the pregnancy rate

Submission date
20/08/2025

Recruitment status
No longer recruiting

Registration date
27/08/2025

Overall study status
Completed

Last Edited
10/09/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Traditionally patients undergoing artificial reproductive technologies (ART) were advised against sexual intercourse, compounded by the fear that intercourse will dislodge the early implanting embryo. Hypothetically sexual intercourse impairs implantation by two principal mechanisms: the introduction of infection and initiation of uterine contractions. In contrast to that, animal studies have demonstrated the positive effect of exposure of seminal fluid component of the ejaculate is important for embryo development and implantation. Sexual intercourse is more natural way of exposure to seminal plasma, and normalizing the conception process will create a positive psychological impact on the couple. Several studies have evaluated on the timing of sexual intercourse around the ART procedure, but results are still inconclusive on improvement in pregnancy rates. The research team postulate that vaginal intercourse with intravaginal ejaculation 96 hours before thawed frozen Day 5 embryo transfer will increase the viable pregnancy rate at 12 weeks gestation as the four-day window of opportunity should create a more conducive environment for implantation. This hypothesis will be tested by advising sexual intercourse compared to advising abstinence within the four-day window preceding Day 5 embryo transfer.

Who can participate?
Women who are undergoing Day 5 frozen embryo transfer (FET) at the UMMC fertility clinic with a medicated FET cycle and an endometrial thickness (ET) of more than 8mm on starting the luteal phase support.

What does the study involve?
The intervention group will be advised to engage in sexual intercourse 96 hours prior to the Day 5 embryo transfer while a control group will be couples advised to abstain from sexual intercourse throughout the cycle.

What are the possible benefits and risks of participating?
Benefits:
Vaginal sex may help improve the chances of pregnancy

It may also support emotional wellbeing during the IVF process
Risks:
There is a possibility that vaginal sex could reduce the chances of pregnancy

Intercourse prior to embryo transfer may have some benefits on pregnancy outcome for patients undergoing IVF treatment in the usual manner (no changes in medication, procedure or appointments). There is a risk of other pregnancy outcomes (ie miscarriage or ectopic pregnancy); that may occur regardless in which arm patient is allocated into.

Where is the study run from?
The fertility clinic at University of Malaya Medical Centre (UMMC), Malaysia.

When is the study starting and how long is it expected to run for?
August 2025 to November 2026

Who is funding the study?
UMMC, Malaysia.

Who is the main contact?
Dr Atikah binti Mohamed Halim, atikah.halim@edu.um.my

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Advising sexual intercourse around embryo transfer: a randomized controlled trial

Acronym
SIET-PR

Study objectives
Sexual intercourse preceding 96 hours prior to embryo transfer improves the pregnancy rate

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/07/2025, Local Institutional Review Board (IRB)/ Independent Ethic Committee (IEC) University Malaya Medical Centre (University Malaya Medical Centre (UMMC), Kuala Lumpur, 59100, Malaysia; +60379494422; ummc-mrec@ummc.edu.my), ref: 2025116-14614

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
In-vitro fertilization

Interventions
Current interventions as of 10/09/2026:
All patients for IVF treatment who have reached the Oocyte Pick Up (OPU) and decided for Frozen Embryo Transfer (FET) will be identified , consent taken at the start of FET cycle, and randomization done once endometrial thickness reached >8mm. Intervention group will be advised to engage in sexual intercourse 96 hours prior to the Day 5 embryo transfer while a control group will be couples advised to abstain from sexual intercourse throughout the cycle. Randomization sequence will be generated online using https://www.sealedenvelope.com /simple-randomiser/v1, in blocks of 4 or 8, following 1 to 1 ratio by a clinic assistant who will not be involved in the recruitment process. Allocation will be sealed in a numbered opaque envelope.

Previous interventions:
All patients decided for Frozen Embryo Transfer (FET) will be identified, informed consent taken at the start of FET cycle, and the randomization will be performed only when endometrial thickness reached >8mm.

Participants will be randomized to
A) Advised to engage in sexual intercourse in the 96 hours prior to the embryo transfer
or
B) Advised to abstain from sexual intercourse through the current IVF cycle

Randomization sequence will be generated online using https://www.sealedenvelope.com /simple-randomiser/v1, in blocks of 4 or 8, following 1 to 1 ratio by a researcher who will not be involved in the recruitment process. Allocation will be sealed in a numbered opaque envelope. The lowest numbered envelopes still available will be allocated to the latest recruit.

Follow up for 10 weeks after embryo transfer.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome as of 10/09/2026:
A viable pregnancy with evidence of intrauterine gestation sac and presence of fetal heart at 10 weeks after Day 5 embryo transfer

Previous primary outcome:
Viable pregnancy with evidence of intra-uterine gestation sac/sacs and presence of fetal heart /hearts activity at 10 weeks after embryo transfer

Key secondary outcome(s)
Current secondary outcome as of 10/09/2026:
1. Implantation rate - the number of gestational sacs observed divided by the number of embryos transferred (usually expressed as a percentage), measured using an ultrasound scan at the end of data collection
2. Other pregnancy outcomes, including miscarriage, ectopic pregnancy, multiple pregnancies, measured using an ultrasound scan at 10 weeks after day 5 embryo transfer

Previous secondary outcome:
1. Implantation rate - the number of gestational sacs observed by ultrasound divided by the number of embryos transferred (usually expressed as a percentage) at 10 weeks after embryo transfer
2. Miscarriage rate - non viable pregnancy diagnosed by ultrasound at 10 weeks after embryo transfer
3. Ectopic pregnancy diagnosed by ultrasound or laparoscopically at 10 weeks after embryo transfer
4. Multiple pregnancies diagnosed by ultrasound scan at 10 weeks after embryo transfer
5. Biochemical pregnancy - serum HCG (>50IU/ml) at 2 weeks after embryo transfer

Completion date
06/11/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 10/09/2026:
1. Women undergoing for frozen embryo transfer

2. Day 5 embryo transfer
3. Medicated FET cycle
4. Endometrial thickness > 8mm on starting the luteal phase support with trilaminar appearance on sonography

Previous key inclusion criteria:
1. Women undergoing for frozen embryo transfer
2. Medicated frozen embryo transfer cycle
3. Endometrial thickness > 8mm on starting the luteal phase support with trilaminar appearance on sonography
4. Embryo transfer (embryo frozen at day 5)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
42 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 10/09/2026:
1. Women undergoing for fresh embryo transfer
2. Endometrial thickness < 8mm on starting of luteal phase support
3. Triple embryo transfer

Previous key exclusion criteria:
1. Fresh embryo transfer
2. Transfer of 3 or more embryos

Date of first enrolment
25/08/2025

Date of final enrolment
28/08/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Wilayah Persekutuan Kuala Lumpur
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	21/07/2025	26/08/2025	No	Yes
Protocol file		05/06/2025	26/08/2025	No	No