

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

Submission date 20/08/2025	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 27/08/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/08/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Around 1 in 6 couples worldwide experience fertility issues. The use of IVF (commonly known as “test tube baby” treatment) has grown significantly, with millions of treatment cycles now performed each year. Most of these involve transferring embryos that were previously frozen. Recent research suggests that sperm and seminal fluid may help prepare the womb for embryo implantation, potentially improving the chances of pregnancy. Even protected sex (using a condom) may have a positive effect. This study aims to find out whether having vaginal sex in the four days before embryo transfer can increase the chances of getting pregnant.

Who can participate?

Women who are undergoing frozen embryo transfer at the UMMC fertility clinic may be eligible if:

- They are on a medicated frozen embryo transfer cycle
- Their womb lining is at least 8mm thick with a healthy appearance on ultrasound
- They are having embryos transferred that were frozen at 5 days old

What does the study involve?

Participants will be randomly placed into one of two groups:

One group will be advised to have vaginal sex in the four days before embryo transfer

The other group will be advised to avoid vaginal sex during the IVF cycle

Participants will be asked to keep a diary of any vaginal intercourse during the study.

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

Where is the study run from?

The study is being run at the fertility clinic at UMMC (University of Malaya Medical Centre) (Malaysia)

When is the study starting and how long is it expected to run for?

February 2025 to December 2026

Who is funding the study?

UMMC (University of Malaya Medical Centre) (Malaysia)

Who is the main contact?

Dr Atikah binti Mohamed Halim, atikah.halim@ummc.edu.my

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Dr Atikah Mohamed Halim

ORCID ID

<https://orcid.org/0009-0006-4131-0613>

Contact details

12 Jalan Aman Taman Robina

Butterworth

Malaysia

13050

+60124907422

atikah.halim@ummc.edu.my

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Advising sexual intercourse before embryo transfer: a randomized controlled trial

Acronym

SIET-PR

Study objectives

Advising sexual intercourse in the 96 hours prior to embryo transfer will increase 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

Study design

A single center parallel group randomized controlled trial with convenience sampling

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

In-vitro fertilization

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 measure

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

Secondary outcome measures

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 ($>50\text{IU/ml}$) at 2 weeks after embryo transfer

Overall study start date

14/02/2025

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Women undergoing for frozen embryo transfer
2. Medicated frozen embryo transfer cycle
3. Endometrial thickness $> 8\text{mm}$ on starting the luteal phase support with trilaminar appearance on sonography
4. Embryo transfer (embryo frozen at day 5)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

42 Years

Sex

Female

Target number of participants

Key exclusion criteria

1. Fresh embryo transfer
2. Transfer of 3 or more embryos

Date of first enrolment

01/10/2025

Date of final enrolment

01/10/2026

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

Sponsor details

Lembah Pantai

Wilayah Persekutuan Kuala Lumpur

Kuala Lumpur

Malaysia

59100

+60 3-7949 4422

ummc-mrec@ummc.edu.my

Sponsor type

Hospital/treatment centre

Website

<http://www.ummc.edu.my/#>

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, UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Results and Publications

Publication and dissemination plan

Planned publication in peer reviewed journal

Intention to publish date

30/06/2027

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

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