

Title: Effect of ejaculatory abstinence on semen parameters in male factor infertility patients: a randomized controlled study

NCT #: **NCT04206800**

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Verbal Consent – Phone call

My name is [research team member] and I am part of Dr. Alan Penzias's research team. Is this [patient name] speaking?

If yes, proceed; if no, ask if [patient name] is available and restart script; if no, thank them for their time and end the call.

I am calling because I am helping Dr. Alan Penzias at Boston IVF with a research study you are eligible for. Our team previously sent an email to you introducing the study. Is now an okay time to talk? The call should take about 5-10 minutes.

If yes, proceed. If not, ask for the best time to call back.

We're following up to see whether you're interested in participating in this research study.

*If yes, proceed to part A.
if no, proceed to part B*

Part A

We are recruiting patients to participate in a study during the IVF cycle. The purpose of the study is to investigate semen parameters and sperm function when men abstain from ejaculation as we have historically advised (> 48 hours) before collecting sperm for the IVF with intracytoplasmic sperm insemination (ICSI) procedure and compare those results to men whose last ejaculation was < 24 hours before collection for IVF. We hope to compare the difference between what we expect will be a higher number of older sperm with somewhat fewer but younger sperm. This study will not change what happens during the IVF treatment and does not require any additional office visits. Men who participate will be asked to complete a short survey and fill in a calendar for ejaculation frequency during the IVF cycle which will be turned in on the day of egg retrieval.

There is no clinical risk to your IVF cycle as the procedures followed are standard clinical practice. Some features of ejaculatory abstinence < 24 hours include lower semen volume and fewer sperm when compared to ejaculatory abstinence > 48 hours. However, all patients in this study are using ICSI to fertilize eggs and the number of sperm needed for treatment will not be compromised by ejaculatory abstinence < 24 hours. We hypothesize that the percentage of total motile sperm will be improved with ejaculatory abstinence less than 24 hours. Previous studies have reported inconclusive results on this topic.

Participation is voluntary. Choosing to participate or not to participate will not affect your care at Boston IVF. You will not benefit directly from participation in this study; however, the information you provide may help future patients.

By consenting to this study, you give us permission to review your medical record and to combine your medical record data and survey responses. The results of this study may be

published but you will not be identified in any publication. We will make every effort to protect the confidentiality of your information. Only members of the research team will have access to protected health information. Participants will be assigned a unique study ID# to protect patient confidentiality.

This study has been approved by the Beth Israel Deaconess Medical Center institutional review board. If you have any questions before, during, or after your participation, you may contact the principal investigator, Dr. Penzias at Bivfresearch@bostonivf.com or by phone (781-434-6500). You also may contact the Human Subjects Protection Office at 617-975-8500 if you would like to talk to someone who is not working on the study.

Randomization

You will be randomly assigned to one of the treatment arms in the middle part the IVF cycle, after your partner has begun taking her medication. A member of the research team will call you with further instructions at that time.

Survey/ejaculation frequency calendar

You received a blank ejaculation frequency calendar and a survey in an envelope from the Boston IVF care team. You can use this to document ejaculation frequency throughout the IVF cycle by writing down the month/date in the blank lines and writing in “S” for ejaculation that occurs during sexual activity with your partner or “M” for masturbation. Please answer the remaining questions. Please bring this document filled out and turn it in to the front desk staff on the day of the egg retrieval prior to providing your semen sample. If you need another copy, we can email it to you today. If you have questions on the instructions of this calendar, please email Bivfresearch@bostonivf.com. The study team understands the survey has questions that are sensitive but only the study team will have access to your responses and will only be used for research purposes. Completing this personal survey has potential for psychological risk including but not limited to: stress, anxiety, apprehension, embarrassment or tension. If at any time during the study you experience these, you may opt out of the survey portion or opt out of the study in entirety.

If you are interested in participating, you may provide verbal consent over the phone. Are you interested in participating? You do not need to come into Boston IVF to sign a new informed consent form. I will alert your physician that you are participating in the study.

Do you have any questions or concerns?

If yes, proceed; if no, thank them for their time and end the call

If yes: would you like to receive a copy of the information discussed via email?

Part B

Okay, thank you for your consideration, and we won't contact you further in regards to this study. *End call*

TO BE FILLED OUT BY RESEARCH STAFF

☐ Participant provided verbal consent

Print Participant's Name: _____

Verbal Consent Obtained By: _____

Date: _____

☐ Emailed participant this form

☐ Participant stated they did not want to receive this form

Contact Information

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Script for phone call voicemail if needed

My name is [research team member] and I am part of the research team helping Dr. Alan Penzias with a research study you are eligible for. This message is for [patient name]. Our team sent an email to you a couple of days ago introducing the study. The research team will try calling again in the next couple of days to see if you're interested in participating. Thank you for your consideration. *End Call*