Category : Study conduct
Title : Birth Control measures for male participants.
SOP No. : D 08/07
Date first effective: 01 Jan 2025 **Review date**: 31 Dec 2025

Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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1. Purpose

The purpose of this SOP is to describe the responsibilities of the research team towards counseling of male participants regarding the birth control measures to be adopted during the study period and the procedures to be followed in case the female partner of the participant is diagnosed to be pregnant during the study period.

2. Scope

This SOP is applicable to all males who are likely to participate in a clinical trial.

3. Responsibilities

Principal investigator, Co-investigator, Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, can counsel male participants regarding the birth control measures to be adopted during the study period.

4. Applicable rules, regulations and guidelines

- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR(2017) http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) ICH E6 (R3) https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)
- Indian GCP guidelines 2001 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ (Last accessed 20 Dec 2024)
- New Drugs and Clinical Trials 2019 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf documents/NewDrugs_CTRules_2019.pdf (Last accessed 20 Dec 2024)

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5. Reference to other applicable SOPs

SOP No. D 03/07: Responsibilities of the Study Team

SOP No. D 15/07: SAE documentation and reporting

SOP No. D 14/07: AE documentation and reporting

6. Detailed Instructions

1. During the screening visit, record and document a detailed medical history of the male participant.
2. Ask the participant regarding the use of any birth control measures by self and/or sexual partner at the present moment, as well as in the recent past.
3. If yes, document the type of birth control method used and advise the participant to continue the same, if the protocol permits that method of contraception.
4. If not, assess the willingness of the participant to adopt birth control measures recommended in the protocol and offer the available options to the participants e.g. condoms for the participant and/or oral contraceptives/barrier contraception/intra uterine device to the female partner following consultation with a Gynecologist.
5. Gynecology consultation should be sought with the relevant OPD of KEM Hospital as decided by the PI.
6. If the participant is not willing to adopt birth control measures and this is necessary as per the protocol, then he cannot be recruited in the study.
7. It is necessary to adequately emphasize the risk of pregnancy of the female partner while the participant is in the study and its consequences and therefore the need for effective contraception.
8. Ensure that the participant understands the importance about reporting to the study physician in case his female partner misses her periods. In such cases, she should be advised to undergo a pregnancy test, obstetric counseling and ultrasonography.
9. In the event that during the study, pregnancy is confirmed, follow the guidelines as for a serious adverse event (SAE) (See SOP D 15/07) and follow the mother through the pregnancy period till delivery to monitor the mother's and baby's health status.

10. If the woman is the partner of the participant, then re-emphasize the importance of preventing a pregnancy during the trial duration and use of appropriate birth control measures to both partners.
11. Always follow the instructions in the protocol regarding withdrawal from the study.

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