

Study of Tolerability, Safety, Pharmacokinetics, Pharmacodynamics and Preliminary Efficacy of the Medicinal Product MediReg®

NCT06869863

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Lomonosov Moscow State University Medical Research and Educational Center
Enrollment	80 participants

Key Eligibility Criteria

Inclusion (6)

- \. Male patients aged 21-60 years at the time of inclusion in the study. 2. Persistent severe disorders of spermatogenesis, manifested as severe oligoasthenoteratozoospermia (OAT)*, non-obstructive azoospermia, high sperm DNA fragmentation (30% or more), including those caused by secretory infertility according to dynamic control of spermogram (at least 12 months from the moment of inclusion in the study).
- "Persistent severe OAT" should be considered as disorders when sperm concentration $\lt 5$ million/mL, progressively motile sperm $\lt 13\%$ and/or total number of progressively motile sperm in the ejaculate (PMPM) $\lt 5$ million, with the proportion of normal sperm $\lt 1\%$ according to the dynamic control of spermogram (at least 12 months from the moment of inclusion in the study).
- \. inability to conceive against the background of "severe forms" of male infertility, not amenable to treatment, including assisted reproductive technologies, within 12 months from the moment of diagnosis or refusal to use assisted reproductive technologies.
- \. Voluntarily signed Informed consent by the patient to participate in the clinical trial.
- \. Willingness of patients and their sexual partners to use reliable contraceptive methods (combination of at least 2 methods, including 1 barrier method, e.g., use of spermicide and condom) from the time of signing the informed consent until at least 1 month after completion of study participation.

... and 1 more (see full listing online)

Exclusion (16)

- \. Age younger than 21 and older than 60 years at the time of inclusion in the study.
- \. developmental anomalies of the genitourinary system (according to bladder and kidney ultrasound).
- \. surgical interventions on genitourinary organs in the history, except for surgical interventions associated with assisted reproductive technologies. 4.
- \. Systemic diseases requiring administration of corticosteroids, cytostatics, radiation therapy.
- \. Inflammatory diseases of the urinary and/or reproductive system. 6. Infectious diseases (including STDs) of the urinary and/or reproductive system.

... and 11 more (see full listing online)

Locations (1 total)

University Clinic of the Medical Scientific and Educational Institute of Moscow State University named after M.V.Lomonosov, Moscow, Moscow, Russia

<https://clinicaltrials.gov/study/NCT06869863>

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