Study Protocol and Statistical Analysis Plan

The effects of carnitine supplementation on oocyte yield and quality in women undergoing IVF

Available evidence indicates that adequate cellular metabolism and sufficient ATP production are essential for achieving optimal oocyte quality, which is a prerequisite for subsequent preimplantation embryo development. Fatty acid metabolism contributes to ATP synthesis within mitochondria through the process of β-oxidation. The transport of fatty acids into mitochondria represents a key step in this process and is catalyzed by carnitine palmitoyltransferase I, which requires the presence of carnitine as a substrate. Although a study conducted at our Clinic demonstrated the importance of appropriate serum and follicular fatty acid concentrations for obtaining a higher number of high-quality oocytes during in vitro fertilization (IVF), it remains unclear whether carnitine supplementation before and/or during IVF treatment could increase the number of oocytes retrieved. The proposed study title is: The impact of carnitine supplementation on the number and quality of oocytes retrieved during in vitro fertilization and IVF outcomes. Women meeting any of the following criteria will be excluded from participation: obesity, use of immunosuppressive therapy, severe renal disease, hepatic insufficiency, and endocrine disorders. The study will include women undergoing IVF treatment at the Gynaecology and Obstetrics Clinic "Narodni Front" who provide written informed consent after receiving detailed information about the study. Recruitment of couples will take place at their first visit to our center, during which the laboratory and diagnostic results required for the IVF procedure are reviewed. Women willing to participate and meeting the inclusion criteria will be allocated into two groups. Participants in the intervention group will receive a supplement containing L-arginine (500 mg), L-carnitine (500 mg), N-acetyl-L-carnitine (250 mg), and myo-inositol (1000 mg), while participants in the control group will not receive supplementation. Participants will be randomized using the sealed-envelope method. After 12 weeks of supplementation and following oocyte retrieval, the number and quality of retrieved oocytes will be assessed as part of the routine and mandatory IVF procedure. In cases where fertilization occurs and embryos are obtained, the number and quality of embryos will also be evaluated as part of the standard IVF protocol. For each participant, serum beta-human chorionic gonadotropin (β-hCG) levels will be measured 13 days after embryo transfer as part of routine IVF care. Biochemical pregnancy will be defined as a β-hCG concentration greater than 50 IU/L. In women with confirmed biochemical pregnancy, a transvaginal ultrasound examination will be performed 35 days after embryo transfer to confirm clinical pregnancy. Sample size calculation indicated that 40 participants are required in the intervention group. An equal number of participants (40) will be recruited into the control group, resulting in a total study population of 80 women.

Assistant Professor Dr. Sci. Med. Milan Perović, the head of the research team

February 13, 2026, Belgrade, Serbia