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O-022 A randomised controlled trial on Recurrent Implantation Failure treatment in a study model performed on women who failed egg donation cycles using GM-CSF (MOLGRAMOSTIM)

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Study question: Is the use of GM-CSF (molgramostim) effective in the treatment of recurrent implantation failure in egg donation cycles?

Summary answer: The clinical use of GM-CSF in women experienced implantation failure in egg donation cycles may be useful.

What is known already: The GM-CSF is a cytokine promoting leukocyte growth as well as trophoblast development. Recurrent implantation failure (RIF) is a clinical entity referring when implantation repeatedly failed to reach a stage recognizable by pelvic ultrasound in IVF cycles. There is no universally accepted definition for RIF. Several factors may determine implantation failure, such as maternal age, embryo aneuploidy, uterine anomalies. The efficacy of a specific treatment is difficult to test in this affection since embryos in general cases show an implantation rate of less than 50%.

Study design, size, duration: The study was conducted to the CERM-Hungaria, Rome, Italy, from the January 2020 to May 2021 on women with recurrent implantation failure after egg donation cycles. Inclusion criteria were: women, aged in between 35-49 years old underwent egg donation cycles with at least three previous transfers with good quality blastocysts that failed to reach pregnancy with no uterine defects (included adenomyosis), no systemic diseases.

Participants/materials, setting, methods: 50 women with recurrent implantation failure after egg donation cycles. Patients were randomly subdivided in two groups: one (25 women) treated with subcutaneous GM-CSF (Molgramostim) 0.3mg/kg/daily from the day before embryo transfer to the b-hcg day. The treatment was continued until the 8th week of gestation: the control group (25 women) was treated with subcutaneous saline solution infusion in the same way of the study group. Primary outcome was the ongoing pregnancy rate.

Main results and the role of chance: Epidemiological data of the two groups did not show statistically significant differences. The ongoing pregnancy rate in the group treated with GM-CSF was 84.0% (21/25) whereas in the control group was 44.0% (11/25), P < 0.0072. The absolute risk reduction was 40.0% (95%CI: 15.8%-64.2%). The NNT was 3.0 (95%CI: 1.6-6.3).

Limitations, reasons for caution: This study has a limited number of patients and more studies are needed to confirm these findings. Furthermore, recurrent implantation failure is a clinical entity difficult to classify and define,
consequently to extrapolate a common indication for all patients with this
should be carefully done.

Wider implications of the findings: The clinical use of GM-CSF in women
experienced implantation failure may be an interesting treatment, if these
data will confirmed, this treatment can be extended to all patients with recur-
rent implantation failure. Furthermore, the study model used may be an inter-
esting way to study recurrent implantation failure.

Trial registration number: NCT01718210