

A randomized clinical trial to evaluate the effect of granulocyte-macrophage colony-stimulating factor (GM-CSF) in embryo culture medium for in vitro fertilization.

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Abstract

OBJECTIVE: To evaluate the effect of granulocyte-macrophage colony-stimulating factor (GM-CSF) in embryo culture medium on ongoing implantation rate (OIR).

DESIGN: Multicenter, randomized, placebo-controlled, double-blinded prospective design.

SETTING: Fourteen Scandinavian fertility clinics.

PATIENT(S): A total of 1,332 women with indication for in vitro fertilization or intracytoplasmic sperm injection; 1,149 received embryo transfer (GM-CSF: n = 564; control: n = 585).

INTERVENTION(S): Oocytes were fertilized, and embryos cultured and transferred in control medium or test medium containing 2 ng/mL GM-CSF.

MAIN OUTCOME MEASURE(S): OIR at gestational week 7, with follow-up at week 12 and birth.

RESULT(S): At week 7, OIRs were 23.5% (GM-CSF), and 20.0% (control) (odds ratio [OR] 1.26, 95% confidence interval [CI] 0.91-1.75). At week 12, OIRs were 23.0% (GM-CSF) and 18.7% (control) (OR 1.35, 95% CI 1.06-1.72), and live birth rates were 28.9% and 24.1%, respectively (OR 1.35, 95% CI 1.03-1.78). The effect of GM-CSF was influenced by the human serum albumin concentration in the medium. Birth weight and abnormality incidence were similar in both groups. Exploratory analyses showed that GM-CSF increased OIR in women with previous miscarriage, especially in women with more than one miscarriage.

CONCLUSION(S): Addition of GM-CSF to embryo culture medium elicits a significant increase in survival of transferred embryos to week 12 and live birth. Our results are consistent with a protective effect of GM-CSF on culture-induced embryo stress. GM-CSF may be particularly efficacious in women with previous miscarriage.

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