

HIGH LIVE BIRTH RATES AFTER SERAGEN LOW DOSE IMMUNIZATION THERAPY (LIT) PRE AND POST PREGNANCY WITH PARTNER LYMPHOCYTES IN PATIENTS WITH RECURRENT MISCARRIAGE (RM)

Study question:

Could Lymphocyte Immunization Therapy effectively improve pregnancy and live birth rate in Unexplained Recurrent Miscarriage patients?

Summary answer:

The use of paternal lymphocytes pre and post pregnancy significantly increases the pregnancy success and Live Birth Rate In Patients With Recurrent Miscarriage (RM)

What is known already:

RM affects 1–2% of couples who attempt to conceive and has been defined as three consecutive pregnancy losses within 20 weeks of pregnancy confirmation. Although many potential causes have been established for RM, about 50% of these remain idiopathic and unexplained owing to immunology factors. Meta-analyses have observed better effectiveness and safety of LIT in treating couples with RM shown improvement in pregnancy outcomes. Still, results are conflicting due to different screening criteria and therapeutic protocols. Objective of present study is to evaluate effectiveness of low dose LIT in patients with uRM and Th1/Th2/Treg paradigm disorders

Study design, size, duration:

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<https://www.indiraivf.com>.

Participants/materials, setting, methods:

Maternal BMI of 30 and age of 45 was upper limit with peripheral blood Th1/Th2/Treg cells proportions and concentrations of TNF- α , IFN- γ , low TGF- β 1, and blocking antibodies were detected by flowcytometry/ELISA, respectively. Per Seragen's personalized dosage protocol from 30-50ml paternal blood, 20-40x10⁶ lymphocytes/3ml saline was intradermally administered to the wife before Embryo Transfer and postpregnancy confirmation

Main results and the role of chance:

Proportion of Th1 cells was significantly decreased while proportions of Th2 cells and Treg cells were significantly increased in immunotherapy patients after treatment. In addition, concentration of TGF- β 1 in serum was significantly higher after immunotherapy than before. Concentration of TNF- α , IFN- γ was significantly high before therapy were significantly decreased after therapy. LIT effectively induced production of blocking antibodies in all the patients. 16/17 (94%) uRM patients underwent ET post LIT became pregnant and 4 of the pregnant patient had delivered healthy babies (23.5%). 47.1% (8/17) of patients have reported uneventful ongoing pregnancies crossed >14weeks. 4 patients who were pregnant for more than 12-14 weeks had miscarriages (23.5%). 1 patient (5.9%) did not conceive. 1 patient (5.3%) conceived spontaneously and crossed 20 weeks of uneventful gestation. 1 patient (5.3%) opted to try to conceive naturally hence ET is not planned.



Parameters	Number of patients	Outcome Percentage (%)
Total number of patients	19	
ET not done/Patient opting to try naturally	1	5.3%
Natural Conception	1	5.3%
ET done	17	89.5%
HCG Positive	16	94.1%
HCG Negative	1	5.9%
Miscarriage	4	23.5%
Live Birth	4	23.5%
Ongoing	8	47.1%
Cumulative positive outcome	13	76.5%

LIT Is Associated With High Live Birth Rates, Especially In Women With RM.

LIT not only ameliorates patient's cellular immune function, but also further increases patient's pregnancy success rate with high safety, which is worthy of clinical application and promotion.

Limitations, reasons for caution:

This prospective self-control study with small sample size lacks randomized control group. Beneficial effects observed in this study are in sync with published data. Larger study with patients recruited on the basis of inclusion criteria of unexplained recurrent miscarriage is proposed for recommending LIT as routine therapy.

Wider implications of the findings:(max. 50 words):

LIT Is Associated With High Live Birth Rates, Especially In Women With Repeated Pregnancy Loss – Miscarriages. Indira IVF -Seragen study findings supports LIT as a beneficial treatment for RM/RIF in IVF patients. LIT may be considered safe and effective therapy in individual cases and based on the immunoprofiling (Th1/Th2/Treg paradigm disorders), after all other potential causes of RM or RIF have been ruled out.

Conflict of interest:

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.