

CLINICAL SUMMARY

Title	Oral dydrogesterone treatment during early pregnancy to prevent recurrent pregnancy loss and its role in modulation of cytokine production: a double-blind, randomized, parallel, placebo-controlled trial
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Objective

To study the impact of administration of dydrogesterone in early pregnancy on pregnancy outcome and its correlation with Th1 and Th2 cytokine levels.

Study Design

- Double-blind, randomized, placebo-controlled, single center study.
- Patients were women with:
 - a history of idiopathic recurrent pregnancy loss (RPL) in either a dydrogesterone group or a placebo group
 - no history of miscarriage

Healthy Control (no RM)	Placebo	Dydrogesterone
n=174	n=173	n=175

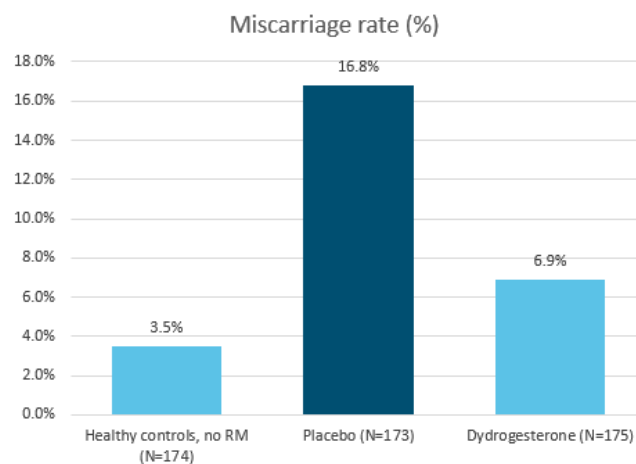
- Dydrogesterone 20 mg/day from confirmation of pregnancy to 20 weeks of gestation.
- Women 18–35 years with ≥ 3 consecutive unexplained recurrent miscarriages
 - Followed by a spontaneous conception (1st trimester of live pregnancy).
- Treatment was given from confirmation of pregnancy preferably at 4–8 weeks of gestation (enrolled after fetal heart activity confirmed) to 20 weeks.

Results

- Occurrence of another abortion after 3 consecutive abortions was significantly higher (16.76%) in women with RPL compared with healthy pregnant controls (3.45%).
- Mean gestational age at delivery (excluding those aborted before 20 weeks of gestation) increased significantly in the dydrogesterone group (38.01 +- 1.96 weeks) compared with the placebo group (37.23 +- 2.41 weeks).

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- Baby weight was significantly lower in the placebo group (2421.4 +- 321.6 g) compared with the healthy pregnant controls (2545.3 +- 554.3 g).
- At recruitment, serum IL-4 and tumor necrosis factor alpha levels were significantly lower in the RPL group compared with the healthy pregnant controls.
- However, serum interferon-gamma level was significantly higher in the RPL group (8.87 +- 0.72 pg/mL) compared with the healthy pregnant controls (8.08 +- 1.27 pg/mL).



Risk of miscarriage was 2.4 times higher in the placebo *versus* dydrogesterone group.
RR: 2.4 (95% CI: 1.3, 5.9); p=0.004

Conclusions

- The study supports the use of dydrogesterone in women with recurrent abortions to improve pregnancy outcome in abortions.
- Outcomes were not modulated by Th1 and Th2 cytokine production.