CLINICAL SUMMARY

Title	Modulating fertility outcome in assisted reproductive technologies by the use of dydrogesterone
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Publication	Gynecological Endocrinology, 2007; 23(S1): 68–72

Objective

To evaluate dydrogesterone for luteal-phase support in assisted reproductive technologies (ART) and to compare it with micronized vaginal progesterone.

Study Design

- Single center study in India.
- The study consisted of two phases. Patients in the first phase received 600mg/day micronized vaginal progesterone (MVP) from the day of oocyte retrieval, in addition with either 20mg/day oral dydrogesterone or the placebo from the day of embryo transfer. Once the results had been established, a second phase was initiated. Patients in the second phase were randomized to receive either 600mg/day MVP or 30mg/day oral dydrogesterone from the day of oocyte retrieval.
- Patients were divided into three groups:
  - long protocol and not at risk of ovarian hyperstimulation syndrome (OHSS) [A, D].
  - long protocol and at risk of OHSS [B, E].
  - Those in a donor oocyte program [C, F].
- Viable pregnancies were confirmed by ultrasonography after 3 weeks.

Results

A total of 498 patients were included in phase I [Table I]:

- 315 patients were on a long protocol and had no risk of OHSS (group A).
- 89 patients were on a long protocol and had a risk of OHSS (E_2>2000 pg/ml; group B).
- 94 were recipients in a donor oocyte program (group C).
- All patients received micronized progesterone with either dydrogesterone (n=218) or placebo (n=280).
- The pregnancy rate was significantly higher in the dydrogesterone in group C. [Table II].

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A total of 675 patients were included in phase II:

- The patients were randomized to receive either dydrogesterone (n=366) or
- micronized progesterone (n=309). [Table III]
- The pregnancy rate was statistically significantly higher with dydrogesterone than with micronized progesterone in groups. [Table IV]

Table I: Patients included in phase I

	Total	Dydrogesterone + micronized progesterone	Placebo + micronized progesterone
Group A long protocol, no risk of OHSS	315	112	203
Group B long protocol, risk of OHSS	89	57	32
Group C donor oocyte program	94	49	45
Total	498	218	280

OHSS: ovarian hyperstimulation syndrome

Table II: Pregnancy rates in phase I

	Dydrogesterone + micronized progesterone	Placebo + micronized progesterone	*p* Value
Group A	37 (33.0)	48 (23.6)	NS
Group B	21 (36.8)	9 (28.1)	NS
Group C	21 (42.9)	7 (15.6)	< 0.001
Total	79 (36.2)	64 (22.9)	

NS: not significant; data are *n (%)*

Table III: Patients included in phase II

	Total	Dydrogesterone	Micronized progesterone
Group D long protocol, no risk of OHSS	450	248	202
Group E long protocol, risk of OHSS	105	60	45
Group F donor oocyte program	120	58	62
Total	675	366	309

OHSS: ovarian hyperstimulation syndrome

Table IV: Pregnancy rates in phase II

	Dydrogesterone	Micronized progesterone	*p* Value
Group D	97 (39.1)	54 (26.7)	< 0.01
Group E	25 (41.2)	16 (35.6)	< 0.01
Group F	28 (48.2)	21 (33.9)	< 0.001
Total	150 (41.0)	91 (29.4)	

Data are *n (%)*

Conclusions

- The authors concluded that, dydrogesterone is an orally active and effective drug for use in luteal-phase support in ART cycles.
- The optimal dose of dydrogesterone in luteal-phase support would appear to be 30 mg/day, although further studies are necessary to confirm this.
- Dydrogesterone was superior to micronized progesterone as it resulted in a higher pregnancy rate and patient compliance is generally better with an orally administered than with a vaginally administered drug.