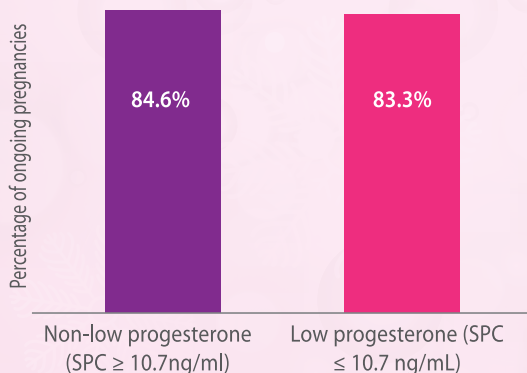


- Vaginal progesterone (VP) alone has been used as luteal support (LS) in hormone replacement therapy – frozen embryo transfer (HRT-FET) cycles without measuring serum progesterone concentrations (SPC).
- It has been observed that serum progesterone levels do not rise sufficiently in some women receiving vaginal progesterone, hence leading to poor outcomes.
- The combined use of vaginal progesterone with other routes of progestins improves the outcomes over vaginal progesterone alone.
- Dydrogesterone supplementation with vaginal progesterone can overcome the lower serum progesterone concentration (SPC) often observed with vaginal progesterone alone.

Pregnancy outcome with vaginal progesterone alone

- Average serum progesterone concentration (SPC) was significantly lower in miscarriage cases (9.6 ng/mL) than ongoing pregnancies (14.7 ng/mL).
- A cut-off value of 10.7 ng/mL was identified as a good predictor for pregnancy outcome.
- Vaginal progesterone alone resulted in lower SPC in some pregnant women in HRT-FET cycles & exhibited a lower ongoing pregnancy rate.

Percentage of ongoing pregnancies by SPC in dydrogesterone with progesterone group



Dydrogesterone with vaginal progesterone

- Similar ongoing pregnancy outcome at the end of 9 weeks of gestation were observed, 84.6% in non-low progesterone (SPC ≥ 10.7ng/ml) group & 83.3% in low progesterone (SPC ≤ 10.7 ng/mL) group.
- Dydrogesterone with vaginal progesterone improved ongoing pregnancy rate of low progesterone cases to the level comparable with non-low progesterone cases.

Co-administration of dydrogesterone with vaginal progesterone offers consistent progestational support, reduces miscarriage and improves ongoing pregnancy rates while being safe, oral and patient-friendly.

Ref.: Reprod Med Biol.2023 Mar 22;22(1):e12511

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Uniquely designed to support **MORE** in gestation



Drug Review

Luteal Phase Insufficiency

- ❶ The luteal phase extends from ovulation to the establishment of pregnancy or the start of menstruation. In this phase, progesterone level increases and prepares endometrial lining for implantation.
- ❷ Any problem with progesterone secretion during the secretory phase leads to defective luteal phase, resulting in embryo implantation failure & pregnancy loss.
- ❸ Luteal phase defect is more evident in the fields of infertility, recurrent pregnancy loss & preterm labor.
- ❹ It is usually seen in women with PCOS, hypothyroidism, hyperprolactinemia & Assisted Reproductive Technology (ART).

Role of Progesterone for Luteal Support in Pregnancy & ART (Assisted Reproductive Technology)

- ❶ Progesterone is the primary 'pro-gestational' hormone in the human body. Progesterone primes endometrial receptivity necessary for embryo implantation & suppress the maternal immunological response to the fetal antigens allowing implantation.
- ❷ Progesterone levels at conception have been found to be linearly associated with miscarriage.
- ❸ Luteal phase support with progesterone supplement is a known intervention for preventing pregnancy loss. Hence, progestogen needs to be used from the beginning of conception to prevent miscarriage.

Conventional Progesterone Preparation and Patients' Inconvenience^{1,2,3,4}

- ❶ Oral progesterone undergoes extensive first-pass hepatic metabolism resulting in its degradation and poor bioavailability of only 2.8%, thus requiring higher doses of progesterone.
- ❷ Additionally, the neurosteroid metabolites of oral micronized progesterone causes undesired side effects like, dizziness, drowsiness, sedation, somnolence and fatigue.
- ❸ Vaginal progesterone has better bioavailability compared to oral form, but patients' compliance is a major concern because of side effects like vaginal discharge, pruritis, vaginal messiness & irritation.
- ❹ Intramuscular (IM) progesterone despite precise dosing can be extremely painful due to local inflammation, abscess & injection site tissue damage from its oil-based preparation.

Dydron- A orally active unique retro-progesterone designed to support **MORE** in gestation⁵

- ❶ Dydrogesterone is a synthetic progesterone with a high specificity to progesterone receptors in the human body.
- ❷ Dydrogesterone belongs to the retro progesterone class shaped by light technology to obtained enhanced progesterone effects compared to natural progesterone.
- ❸ Thus, Dydrogesterone achieves,
 - **More Potency & Stability:** 10-20x more potent than progesterone
 - **Oral Bioavailability:** 5.6 x higher compared to progesterone
 - **Receptor Binding Affinity:** 1.5x higher than progesterone
 - **Extraordinary Clinical Benefits:** Compared to progesterone

Ref: 1. Gautam N, Allahbadia. Has ART Finally Got a Patient-Friendly Progesterone? The Journal of Obstetrics and Gynecology of India (September–October 2015) 65(5):289–292.; 2. Ashraf Moini, Arezoo Arabipoor, Zahra Zolfaghari, et. al. Subcutaneous progesterone (Prolutex) versus vaginal (Cydgest) for luteal phase support in IVF/ICSI cycles: a randomized controlled clinical trial. Middle East Fertility Society Journal (2022) 27:16.; 3. Levine H, Watson N (March 2000). "Comparison of the pharmacokinetics of Crinone 8% administered vaginally versus Prometrium administered orally in postmenopausal women(3)". Fertil. Steril. 73 (3): 516–21.; 4. Wang-Cheng R, Neuner JM, Barnabei VM (2007). Menopause. ACP Press. p. 97. ISBN 978-1-930513-83-9.; 5. Georg Griesinger, Herman Tournaye, Nick Macklon, Felice Petraglia, Petra Arck, Christophe Blockeel, Peter van Amsterdam, Claire Pexman-Fieth, Bart CJM Fauser ; Dydrogesterone: pharmacological profile and mechanism of action as luteal phase support in assisted reproduction;

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