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No additional risk of congenital anomalies after first-trimester dydrogesterone use: a systematic review & meta-analysis

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Is exposure to dydrogesterone a risk factor for congenital anomalies when given in the first trimester for recurrent/threatened pregnancy loss or as luteal support in assisted reproductive technology (ART)?

Method: A systematic literature review and meta-analysis was done on-

- 6 randomized controlled trials (RCTS)
- 3 observational studies (OSs)

Participants: Women >17 years old treated for threatened miscarriage, recurrent pregnancy loss, &/or ART

N 5070

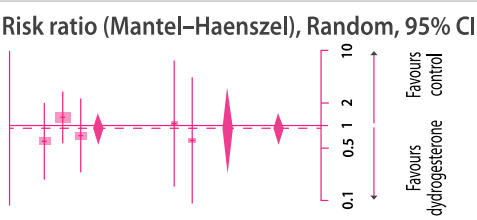
Live births 2680

Dydrogesterone in the first trimester compared with placebo

Primary outcome: Congenital anomalies in newborns or infants ≤ 12 months old

RISK

In the meta-analysis of RCTs only, the overall risk ratio (RR) was 0.92 with low certainty. When the two OSs were included, the overall RR was 1.11 with low certainty.



The overall prevalence of congenital anomalies associated with dydrogesterone in the given indications was **2.5%** for dydrogesterone-exposed live births which is within normal range of all anomalies in still and live births of 2021.

2.5%

Summary: Dydrogesterone, when given in the first trimester for recurrent/threatened pregnancy loss or as luteal support in ART, is not a relevant additional risk factor for congenital anomalies

Ref.: Katalinic, Alexander et al. "No additional risk of congenital anomalies after first-trimester dydrogesterone use: a systematic review and meta-analysis." Human reproduction open vol. 2024,1 hoae004. 23 Jan. 2024, doi:10.1093/hropen/hoae004

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Summary of the diagnosis and treatments of RPL (ESHRE-2022)

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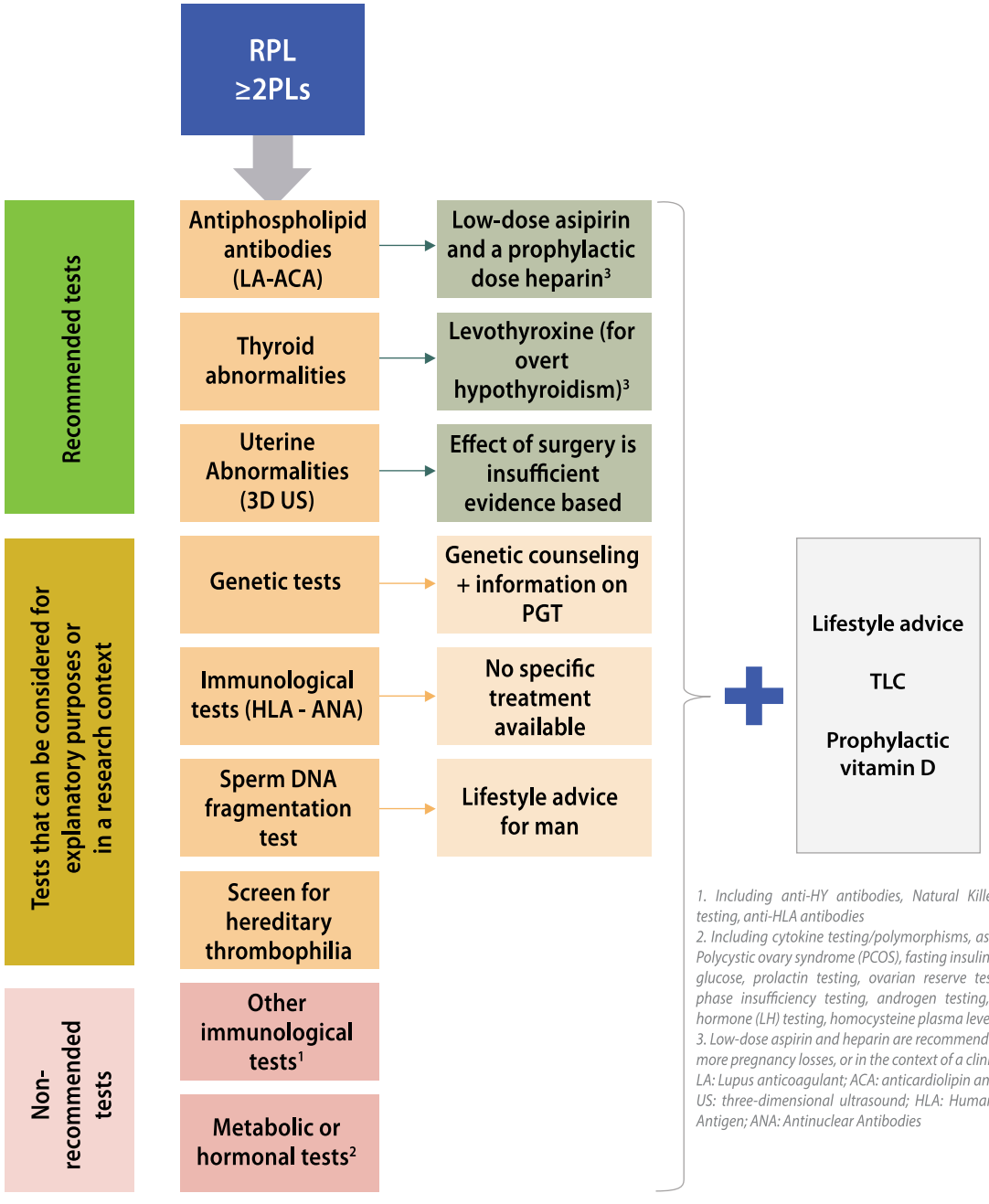

1. Including anti-HY antibodies, Natural Killer (NK) cell testing, anti-HLA antibodies
2. Including cytokine testing/polymorphisms, assessment of Polycystic ovary syndrome (PCOS), fasting insulin and fasting glucose, prolactin testing, ovarian reserve testing, luteal phase insufficiency testing, androgen testing, luteinizing hormone (LH) testing, homocysteine plasma levels
3. Low-dose aspirin and heparin are recommended after 3 or more pregnancy losses, or in the context of a clinical trial.
LA: Lupus anticoagulant; ACA: anticardiolipin antibodies; 3D US: three-dimensional ultrasound; HLA: Human Leukocyte Antigen; ANA: Antinuclear Antibodies

Ref.: ESHRE Guideline Group on RPL et al. "ESHRE guideline: recurrent pregnancy loss: an update in 2022." Human reproduction open vol. 2023,1 hoad002. 2 Mar. 2023, doi:10.1093/hropen/hoad002

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