PRELIMINARY STUDY TO EVALUATE THE EFFECTS OF MYO-INOSITOL (MYO) IN PCOS PATIENTS UNDER OVULATION INDUCTION WITH OR WITHOUT ASSISTED REPRODUCTIVE TECHNIQUES (ART)

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Rationale: MYO is a natural endogenous mediator of insulin action and its production has been shown to be insufficient in insulin-resistant states, such as in PCOS. In literature, dietary supplementation with MYO has yielded varying results on PCOS symptoms.

Materials and Methods:
- Patients are recruited during their infertility work including a complete hormonal assessment and a vaginal ultrasound. Inclusion criteria are high antral follicle count (AFC) (> 19 per ovary) and oligo-anovulation and/or clinical hyperandrogenism. The aim is to include 30 patients submitted to simple (i.e., no ART) ovulation induction and 30 patients undergoing controlled ovarian hyperstimulation for ART (IUI or IVF).
- MYO supplementation consists in 2 tablets per day of INOFOLIC ® (0.6 g myo-inositol + 0.1 mg of folic acid) given in addition to 0.4 mg of folic acid usually prescribed. Supplementation is started on average 2 months before the onset of stimulation and continued for 3 months for the simple ovulation induction group and 4 months for the stimulation group for IVF or IUI.

Results:
The parameters analysed will be:
- Age, waist circumference, BMI, AFC and serum AMH, LH, FSH, E2, SHBG, HDL-C and androgen levels collected at baseline and after 2 months of supplementation before starting the stimulation. This will be done only in the simple ovulation induction group as this protocol does not fit with the agenda of patients undergoing ART.
- Main outcomes of ovulation induction for the two groups:
  - Response to stimulation
  - Cancellation rate of cycles
  - Rates of pregnancy and evolution
- The control group (supplemented with 0.4 mg folic acid only) will be made by matching retrospectively patients with similar features: age, duration of infertility, TT, BMI, etc.

To date, 45 patients have been included in both study groups. Two pregnancies were achieved under MYO in the simple induction group.

Perspectives
If this preliminary study showed promising results, a larger randomised double-blinded multi-centric study will be conducted in France.