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ConFIRM trial - conversion of in vitro fertilization cycles to intrauterine inseminations in patients with a poor ovarian response to stimulation: a protocol for a multicentric, prospective randomized trial

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Auteur	Delbos, Léa [1], Parot-Schinkel, Elsa [2], El Hachem, Hady [3], Legendre, Guillaume [4], Descamps, Philippe [5], Boucret, Lisa [6], Ferré-L'Hotellier, Véronique [7], Jeanneteau, Pauline [8], Dreux, Cécile [9], Morinière, Catherine [10], May-Panloup, Pascale [11], Bouet, Pierre-Emmanuel [12]
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Résumé en anglais	Background To date, there is no consensus on the ideal management strategy of patients with poor ovarian response (POR) to controlled ovarian stimulation (COS) for in vitro fertilization (IVF). Currently, these patients are given the choice of: (1) canceling the cycle; (2) proceeding with COS regardless of the poor response, and performing the oocyte retrieval and transfer of embryos when available; or (3) conversion to an intrauterine insemination (IUI). When the decision to proceed with the COS cycle is taken, it is not clear whether IVF or conversion to IUI is the best choice. If live birth rates were comparable between the two strategies, conversion to IUI would be the better option for poor responders, since it is less invasive and is associated with a lower cost. Methods We designed a non-inferiority, multicentric, randomized controlled trial that will be conducted in 18 French Reproductive Medicine centers. We defined POR as the presence of only two or four mature follicles ≥ 14 mm on ovulation trigger day. Patients with POR will be randomized into two parallel arms: “IVF” and “conversion to IUI.” Our main objective is to compare the efficiency of IVF and conversion to IUI in patients with POR to COS. The primary outcome is the live birth rate, defined as the birth of a living infant after 22 weeks’ gestational age, or weighing ≥ 500 g. One of the secondary objectives is to compare the cost-efficiency of both strategies at 12 months. We will need to include 940 patients (470 in each arm), and the duration of the inclusion period is estimated to be 36 months. Discussion This is the first randomized controlled trial to compare the outcomes of IVF and embryo transfer to conversion to IUI in patients with POR to COS. If our study shows that conversion to IUI is non-inferior to IVF in terms of clinical efficiency and live birth rate, it would confirm IUI as a better alternative for patients, both individually (less invasive and more patient-friendly) and collectively (lower cost).
URL de la notice	http://okina.univ-angers.fr/publications/ua18029 [16]
DOI	10.1186/s13063-018-2936-5 [17]
Lien vers le document	https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2936-5 [18]
Titre abrégé	Trials

Liens

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