66. EFFORT study: Comparing impact of operation and assisted reproductive

technologies on fertility for women with deep infiltrating endometriosis - study

protocol for a multicentre randomised trial

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Abstract

Introduction: Deep infiltrating endometriosis (DIE) affecting the rectum or sigmoid colon is

associated with infertility, severe pain and decreased quality of life. As most women with

DIE are young, many have a pregnancy intention. Treatment possibilities of endometriosisassociated

infertility are surgery or assisted reproductive technologies (ART). However, no

studies have compared the two interventions directly. Therefore, this study aims to determine

the cumulative pregnancy rate (CPR) and the live birth rate (LBR) after first-line surgery

compared with first-line ART for women with rectosigmoid DIE and a pregnancy intention.

Methods and analysis: Multicentre, parallel-group, randomised trial of women with

rectosigmoid DIE and a pregnancy intention for at least 6 months in Aarhus, Denmark and

Bordeaux, France. 352 women aged 18-38 years are randomised 1:1 to either surgical

management (shaving, disc excision or segmental resection) or ART management (at least

two in vitro fertilisation or intracytoplasmic sperm injection procedures if not pregnant after

the first cycle). Women in the surgical intervention group will attempt to get pregnant by

either spontaneous conception or ART, depending on the endometriosis fertility index score.

Primary outcome measures are CPR and LBR at 18 months' follow-up. Secondary outcomes

are: Non-viable pregnancies, time to pregnancy, pain score, quality of life, complication rate,

bowel and bladder function, endocrine and inflammatory profile, number of oocytes,

blastocysts, frozen embryos and blastocyst morphology score within 18 months after either

intervention.

Ethics and dissemination: Conduct of this study is approved by the Danish National

Committee on Health Research Ethics and Comit. de Protection des Personnes Ile de France

VIII. Study participants must sign an informed consent form. The results will be presented at

national and international conferences and published in international peer-reviewed journals.

Trial registration number: This trial is registered at ClinicalTrials.gov (no. NCT04610710).

Protocol version: The Danish National Committee on Health Research Ethics: Fifth protocol

version approved 7 September 2020 (no. 1-10-72-96-20). Comit. de Protection des Personnes

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Keywords: Minimally invasive surgery; Reproductive medicine; Subfertility.