

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

Title (Provisional)

Tubal flushing with oil-based contrast during hysterosalpingography versus tubal flushing by hysterosalpingo-foam sonography in infertile women undergoing fertility work-up: study protocol of a randomized controlled trial (FOil study)

Authors

Kamphuis, Danah; Huijser, Janette; van Welie, Nienke; Verhoeve, H.R.; Kuijper, Esther; de Bruin, J.P.; van Dongen, A.; Gielen, Susanne J.C.M.; de Krom, Guusje; Janse, Femi; Koks, C.A.M.; Nap, Annemiek W.; Anema, Johannes; Bosmans, J; Stoker, Jaap; van Wely, Madelon; Mol, Ben W; Mijatovic, Velja; Dreyer, Kim

VERSION 1 - REVIEW

Reviewer	1
Name	Petrova, Guenka
Affiliation	Medical University of Sofia, Bulgaria., Faculty of Pharmacy
Date	24-Oct-2024
COI	

Dear Authors, my only concern is the following:

In the introduction, as well as in the beginning of the discussion section you mentioned that HyFoSy is less painful alternative to traditional HSG and has the potential for high chance for conceiving. From the other side the study is unblinded. So my concern is whether you will inform women for this difference in both methods and how you will ensure randomisation if they prefer the HyFoSy testing.

VERSION 1 - AUTHOR RESPONSE

I. Reviewer: 1
Reviewer 1, comment 1

A. Reviewer	In the introduction, as well as in the beginning of the discussion section you mentioned that HyFoSy is less painful alternative to traditional HSG and has the potential for high chance for conceiving. From the other side the study is unblinded. So my concern is whether you will inform women for this difference in both methods and how you will ensure randomisation if they prefer the HyFoSy testing.
B. Response	We thank the reviewer for their comment and we understand their concern. As mentioned in the patient information letter, we will inform potential participants that most women experience HyFoSy as less painful compared to HSG, but that it is still unknown whether tubal flushing by HyFoSy increases pregnancy chances. Women can outweigh the characteristics of each test and decide whether they want to participate in this randomized controlled trial. We experience that some women have a preference for either of the two tests, but about 50% of the eligible women is willing to participate after reading the information.
C. Changes made	We emphasised the lack of randomized controlled trials on the therapeutic effects of HyFoSy in the introduction and changed: 'To date, the therapeutic effects of tubal flushing by HyFoSy have only been studied in observational studies with limited sample size, lacking a control group.' into 'To date, randomized controlled trial on the therapeutic effects of tubal flushing by HyFoSy are lacking. Pregnancy rates after HyFoSy have only been reported only been reported in observational studies with limited sample size, lacking a control group.'
D. Location of changes	Lines 111-112