Reviewer’s report

Title: Pilot randomized trial of short-term changes in inflammation and lipid levels during and after aspirin and pravastatin therapy

Version: 0 Date: 24 Jun 2019

Reviewer: Keely Kringlen

Reviewer's report:

I used the CONSORT 2010 checklist to review the article and these are some of the questions and comments that I had.

Study Design: Randomized Trial

Primary Research Objective: Short-term effects of statin in obese and overweight women with systematic inflammation using aspirin to improve fertility outcomes. "Our goal was to characterize short-term changes in inflammatory and lipid biomarkers during and after treatment." The objective is clearly stated.

Plain English:

Line 34: Why do these conditions impair fertility? (Answered in line 52)

Line 35: How do these drugs treat infertility? What is a statin? (line 64) If aspirin is safe to take during pregnancy what is the significance of including aspirin in the study? (perhaps eluded to in line 60 and beyond)

Background:

Background looked great. It answered all of the questions that I originally had in the plain English section.

Scientific explanation and rationale explained.

Hypothesis defined: "For women with higher adiposity, a 62 higher dose of aspirin may be necessary, and a dual therapy targeting both inflammation and lipid levels may provide additional benefit and be needed to improve reproductive outcomes."

"In addition to aspirin, statin drugs may be beneficial in addressing infertility."
Methods:

Trial Design: open-label randomized trial

Sample Size Determination: How was the sample size determined? Was there a limit on size for example?

Line 86: how were the doses of each medication determined?

Line 87: how was the time period of medication intake and washout determined? Where there specifications on the time of day that the medication was to be taken orally?

Results:

Line 108: What method was used to randomize the women into treatment groups? Was there any blinding of the participants?

This might be important since the "randomized design of the study" is listed as a strength in the discussion section.

Do precision values need to be included for median and ranges?

Discussion:

The discussion section was great. Strengths and limitations are outlined, authors linked findings to others studies and discussed differences, and discussed study validity.

Any potential harm or adverse effects of the medication?

Conclusion:

Conclusion seemed a little short. Data presented supports authors conclusions. In the future larger randomized trial, will the population be the same? How can this trial be included into public health and clinical work?

Level of interest
Please indicate how interesting you found the manuscript:

An exceptional article
Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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