A PILOT TRIAL ON THE OUTCOMES OF FERTILITY SPARING TREATMENT OF ATYPICAL ENDOMETRIAL HYPERPLASIA

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Abstract Body

Objective

Atypical endometrial hyperplasia (AH) is a growing clinical problem that increases the risk of carcinogenesis and negatively impacts fertility. To-date, there has been no RCTs evaluating the performance of Mirena versus megestrol acetate (Megace) in treating women with atypical hyperplasia who still desire fertility.

Materials and Methods

The study team conducted a multi-centre randomised controlled trial on the use of Mirena compared to Megace in the treatment of AH from January 2020 to the present. Women ≤ 40 years old diagnosed with AH were included in the study. The patients were randomised to either the Mirena arm or the Megace arm and underwent endometrial biopsy after 3 months of treatment to assess for regression. Patients with persistent disease were continued on the treatment up to a maximum treatment duration of 9 months.

The primary outcome assessed was the regression rate. The secondary outcomes assessed include side effects, patient acceptability and fertility outcomes.

Results

Preliminary analysis was performed on the first 31 patients recruited into the study. The mean age was 32.7 years and the mean BMI was 36.6 (range: 20 – 55.9). 35.4% of patients had diabetes or pre-diabetes and 41.9% had polycystic ovarian syndrome.

Among the 31 patients, 23 patients have completed the trial by June 2022. The overall regression rate was 87.0% by 9 months. Two patients (8.7%) had persistent disease at 9 months and 1 patient (4.3%) had progression to cancer. 91.7% of patients in the Mirena arm regressed by 9 months compared to 81.8% in the Megace arm, although the difference was not statistically significant. There was no significant difference in side effects and weight change in both arms.

Conclusion

Preliminary data confirms a high regression rate of AH with medical treatment. Mirena is a non-inferior treatment compared to megestrol acetate.