Palmitoylethanolamide and Polydatin effect on pain and dysmenorrhea in women scheduled for laparoscopic treatment of possible endometriosis: a double blind randomised controlled trial

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Introduction

Endometriosis effects at least 10% of reproductive age females worldwide; Effective medical therapies for the treatment of endometriosis related pelvic pain are limited and are often associated with side-effects.

Palmitoylethanolamide (PEA) is a food supplement that has been shown to have anti-inflammatory action.

Polydatin (PLD) is also a food supplement that has antioxidant and pain inhibiting activities.

There have been some small studies performed to assess if the combination of PEA/PLD is helpful for persistent pain associated with endometriosis. The results suggest it might have benefit, but further studies are required.

Aims

The aim of this double blinded randomised control trial is to determine if treatment with PEA/PLD improves endometriosis associated pain. The number of planned participants for this study is 260 in total.

Methodology

Patients who are booked for surgical treatment of possible endometriosis will be offered participation in this study at participating hospitals. Participation will not change their surgeon's care plan, as the supplements are able to be taken during the wait period for surgery. Once consented, participants are randomised to either receive 8 weeks of PEA/PLD treatment or placebo prior to their surgery. Endometriosis will then be confirmed or excluded during the surgery.

Participants will also complete multiple surveys during a 6 month period, which includes pain and quality of life assessments. A baseline survey is completed prior to the commencement of the supplements and also at the conclusion of the 8-week period, ahead of surgery. The final survey is completed at the 6 months timepoint (4 months after surgery).

At the conclusion of this study, the change in pain scores and quality of life scores between the 2 groups will be accessed and compared, to determine if PEA/PLD is beneficial to patients undergoing investigations for endometriosis.

Results

As of 30 September 2022, there has been 67 patients recruited to this study. Of the 67, there are 57 participants actively participating in the PEA/PLD study and 10 patients have been withdrawn from active participation.

Active recruitment commenced in July 2021, predominately at the Royal Women's Hospital and Mercy Hospital for Women. A total of 7 sites have ethics approval for the PEA/PLD study (Figure 1):

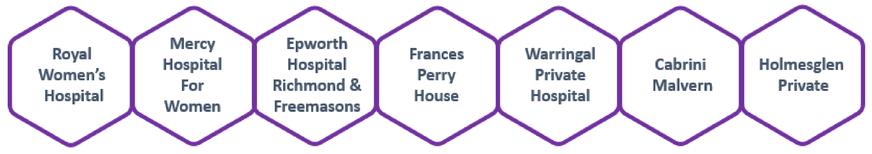

Figure 1: Recruitment sites

The mean age of current participants is 28.4 (SD 7.0) and 40 (70.1%) patients have undergone surgery since recruitment.

Of the 40 participants that have undergone surgery, there has been a 91% compliance rate with the correct number of supplements consumed during the 8-week pre-operative period.

Non-compliance (9%) was due to:

- Patients wanting to just focus on surgery and not participate in research
- Underestimated their commitment to the study
- Unexpected changes in surgery dates (<8 w)
- Not taking supplements correctly (i.e. twice a day).

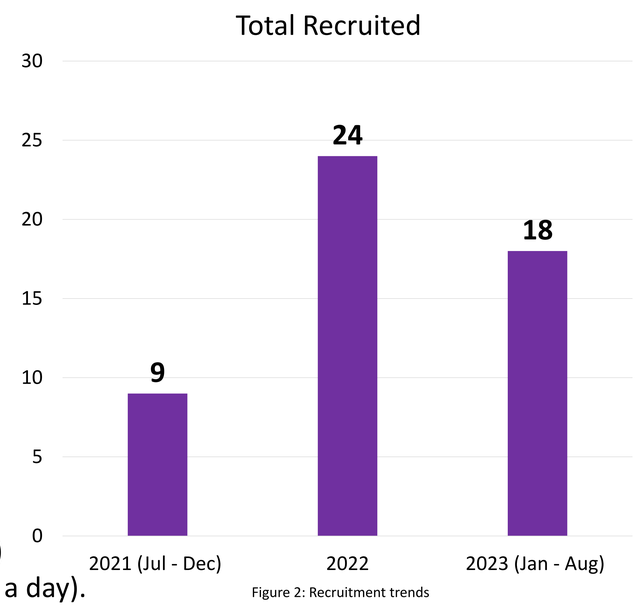

Figure 2: Recruitment trends

There has been no adverse events recorded.

Recruitment Challenges:

- Private recruitment - the time to surgery is short therefore patients are not suitable.
- COVID and the restrictions at the beginning of the study