PRE-EMPT Trial

Background

The PRE-EMPT Trial: Preventing Recurrence of Endometriosis by Means of long acting Progestogen Therapy

Endometriosis is a common condition where cells similar to those within the lining of the womb are found in abnormal locations elsewhere in the body, commonly within the pelvis. Like the lining of the womb itself, these cells respond to oestrogen produced by the ovaries and go through a phase of growth followed by breakdown and bleeding. This internal bleeding within the pelvis causes inflammation, the formation of scar tissue (adhesions) and is associated with pain. Endometriosis occurs in 6-10% of women of reproductive age.

The condition is painful and can have a serious impact on their lives. Many will need surgery to remove areas of endometriosis in order to relieve pain . However, symptoms of endometriosis tend to return and women need to go through repeated surgery including removal of their womb and ovaries.

Endometriosis costs the UK >£2.8 billion/year in loss of productivity mainly due to associated pelvic pain symptoms. Drugs which reduce levels of oestrogen can prevent the re-growth of endometriosis. Previous research has suggested that medicines containing other hormones such as progestogens can reduce the chances of symptoms returning. However, these studies were done with small numbers of participants and were unable to provide definitive results.

We now wish to carry out a large randomised controlled clinical trial in which women undergoing surgery for endometriosis will be randomly allocated to take long acting progestogens (either as three monthly injections or as an intra-uterine device (coil), or long term treatment with the oral contraceptive pill or no treatment. The trial will provide information on which treatment is the most effective in terms of symptom relief, side-effects, acceptability and costs. This information will be vital in terms of future clinical decision making in an area of uncertainty.

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