Effectiveness and cost-effectiveness of Levonorgestrel containing Intrauterine system in Primary care against Standard treatment for Menorrhagia (ECLIPSE)

Background

Heavy menstrual bleeding (HMB) is a common problem that can significantly impact on women's lives, and burden individuals and healthcare systems. A range of non-hormonal and hormonal medical treatments are available as first line therapy for women presenting with HMB in primary care.

The levonorgestrel-releasing intrauterine system (LNG-IUS; Mirena®) was developed as a contraceptive, but it also reduces menstrual blood loss. In 2007, UK guidance introduced the option of LNG-IUS for HMB based on limited evidence.

To date, only small studies have compared LNG-IUS to non-hormonal and hormonal treatments, showing reduction in menstrual blood loss. However, short-term improvement in menstrual blood loss may not reflect the longer term effects of experiencing HMB, particularly as LNG-IUS discontinuation rates are high. Moreover, none of these trials measured the effect of HMB on women's lives nor followed women for longer than one year.

What was the ECLIPSE Trial?

We undertook the ECLIPSE trial, a pragmatic, multicentre, randomised controlled trial designed to assess the clinical effectiveness of LNG-IUS for HMB compared with usual medical treatment in primary care. Initially, we considered outcomes for women after 2 years of follow-up.

Women aged between 25 and 50 presenting to their GPs with HMB, occurring over at least three consecutive cycles, were considered eligible. Consenting women were randomised to having a LNG-IUS fitted, or usual medical treatment, chosen as clinically appropriate to needs by the woman and her doctor.

The usual medical treatment options were mefenamic acid, tranexamic acid, norethisterone, the combined oral contraceptive pill (any formulation), desogestrel or methoxyprogesterone acetate injection. Subsequently, treatments could be changed between the usual medical treatment options, from the LNG-IUS to other medical treatments, or vice versa, or could be ceased completely in line with usual clinical practice (e.g. due to perceived lack of benefit, side effects, change in need for contraception, referral for endometrial ablation or hysterectomy).

The primary outcome measure was the condition-specific questionnaire designed to capture the impact of HMB on women's day-to-day life. Summary scores range from 0 (not affected) to 100 (worst affected).

What did the study find?

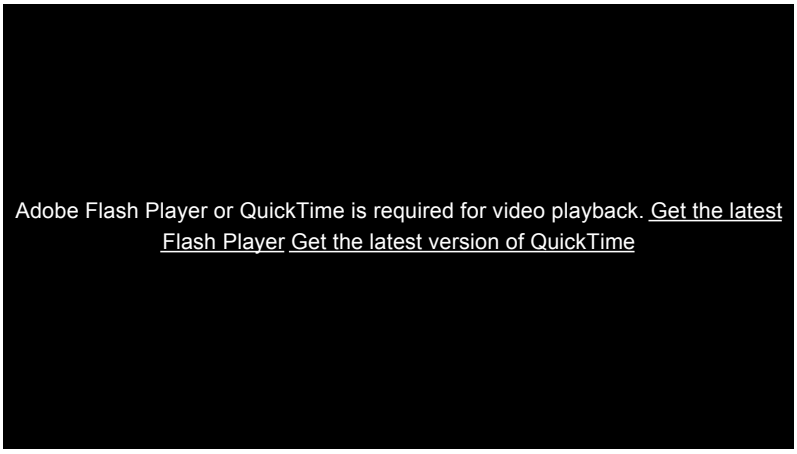
571 women with HMB from 63 UK centers were randomised between February 2005 and July 2009.

The results of the trial have been analysed and submitted to the New England Journal of Medicine.

Levonorgestrel Intrauterine System versus Medical Therapy for Menorrhagia Janesh Gupta, M.D., Joe Kai, M.D., Lee Middleton, M.Sc., Helen Pattison, Ph.D., Richard Gray, M.Sc., and Jane Daniels, M.Sc. for the ECLIPSE Trial Collaborative Group. **N Engl J Med 2013; 368:128-137 (http://www.nejm.org/doi/full/10.1056/NEJMoa1204724)**

You can also find this article via PubMed, please click **here (http://www.ncbi.nlm.nih.gov/pubmed/23301731)**

View interview with Professor Joe Kai regarding results:



The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS or the Department of Health.

What impact will this study have?

We already know that both LNG-IUS and usual medical treatments reduce the adverse impact of HMB on women's lives. The results of the ECLIPSE trial will establish which of the approaches is the most effective.

Publications

The study was funded by the **NIHR Health Technology Assessment program (http://www.hta.ac.uk/project/1374.asp)**

For more information

National Institute of Health and Clinical Excellence (NICE) clinical guidance on heavy menstrual bleeding (http://guidance.nice.org.uk/CG44/PublicInfo/doc/English)

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