

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?

The ECLIPSE trial randomly assigned 571 women with heavy menstrual bleeding to treatment with the coil (LNG-IUS) or usual medical treatment. Women we asked to assess the impact their periods had on their daily life, at intervals over a five year period.

All participants found that their symptoms and quality of life significantly improved, regardless of which treatment they started with. However, the results show that LNG-IUS, as compared with usual medical therapies, leads to greater improvement, over two years, in women's assessments of the effect of HMB on their daily routine, including work, social and family life, and psychological and physical well-being. These findings were no longer significantly different at five years.

Not all women continued with the treatment: by five years, just over half had had the coil removed due to unpredictable bleeding and 85% of those taking pills had changed treatments, mainly to the coil, or stopped treatment. One in five women in each group went on to have surgery e.g. hysterectomy. We could not conclude that the coil was definitely a cost-effective treatment because the results differed depending on the calculation used.

What impact will this study have?

The results provide unique and valuable practical information for women and primary care practitioners when considering choice of, and what to expect from, medical treatments for HMB. Our clinical results support the NICE guidelines that recommend that medical treatment options should be considered when women initially present with HMB in primary care, and that LNG-IUS should be considered first. Women with HMB, a relatively normal sized uterus on examination and no other risk factors can be successfully treated and expect a significant reduction in the range of negative impacts of HMB on quality of life. While LNG-IUS is more effective in this regard than other usual medical options within the first two years of treatment, both LNG-IUS and usual medical treatments are shown to be helpful initial choices five years later. The low overall rates of surgery underline the importance and feasibility of initial medical management of women with HMB in primary care, and the avoidance of referral to secondary care.

The ECLIPSE team thanks all the women who took part in the Eclipse Trial

View interview with Professor Joe Kai regarding results:

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Publications

1. A randomised controlled trial of effectiveness and cost effectiveness of levonorgestrel containing intrauterine system in primary care against standard treatment for menorrhagia – the Eclipse Trial. Gupta JK, Daniels JP, Middleton L, Pattison HM, Prilezky G, Roberts TE, Sanghera S, Barton P, Gray R, Kai J on behalf of the Eclipse Collaborative Group. *Health Tech Assess* 2015. <http://www.nets.nihr.ac.uk/projects/hta/020602> (<http://www.nets.nihr.ac.uk/projects/hta/020602>)
2. Levonorgestrel intrauterine system compared to usual medical treatment for heavy menstrual bleeding. Gupta JK, Kai J, Middleton L, Pattison H, Gray R, Daniels JP. *N Engl J Med* 2013;368(2):128-37 <http://www.nejm.org/doi/full/10.1056/NEJMoa1204724> (<http://www.nejm.org/doi/full/10.1056/NEJMoa1204724>)
3. Levonorgestrel-Releasing Intrauterine System vs. Usual Medical Treatment for Menorrhagia: An Economic Evaluation Alongside a Randomised Controlled Trial. Sanghera S, Roberts TE, Barton P, Frew E, Daniels J, et al. (2014). *PLoS ONE* 2014; 9(3): e91891. doi:10.1371/journal.pone.0091891
4. The measurement properties of the menorrhagia multi-attribute quality-of-life scale: a psychometric analysis Pattison H, Daniels J, Kai J, Gupta J.. *BJOG*. 2011 Jul 27. doi: 10.1111/j.1471-0528.2011.03057.x.

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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