

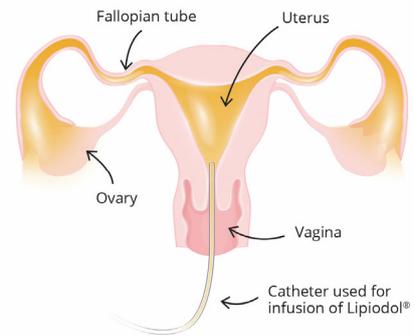
UK approves Lipiodol® Ultra Fluid for hysterosalpingography in women undergoing infertility workup

Villepinte (France) – December 8, 2020 - 06:00pm - Guerbet (GBT) has been granted approval for an indication extension in the United Kingdom, where Lipiodol® Ultra Fluid is the only oil-based contrast medium indicated for hysterosalpingography (HSG) in women undergoing infertility workup. New clinical evidence showing that an HSG with Lipiodol® Ultra Fluid enhances pregnancy rates has been recognized by the UK's Medicines and Healthcare products Regulatory Authority (MHRA). MHRA's endorsement of evidence-based clinical practice confirms the benefit of Lipiodol Ultra Fluid® in fertility management.^{1,2,3,4,5,6}

One in seven couples face fertility issues in the UK.⁷ The fertility workup, during which HSG is performed, is a key step in patient care management.

The technique involves the slow infusion of Lipiodol® Ultra Fluid into the uterus, using x-ray monitoring to assess the uterine cavity and tubes.

More importantly, women who underwent an HSG with Lipiodol® Ultra Fluid had enhanced pregnancy outcomes:



- In a single center randomized trial: in a group of women with unexplained infertility or endometriosis who received Lipiodol® Ultra Fluid (n=73), twice as many became pregnant within six months compared to women who did not benefit from the procedure (n=85). The pregnancy rate was 38.4% and 16.5% respectively (p=0.002).^{2,3}
- In a multicenter randomized trial: in a group of women who underwent an HSG with Lipiodol® Ultra Fluid (n=554), 37% more became pregnant within six months compared to women who received an HSG with a water-based contrast medium (n=554). The pregnancy rate was 39.7% and 29.1% respectively (rate ratio (RR) 1.37 [1.16; 1.61], p<0.001).¹

¹ Dreyer K et al. Oil-based or water-based contrast for hysterosalpingography in infertile women. *N Engl J Med.* 2017 May 25;376(21):2043-52.

² Johnson NP et al. The FLUSH trial--flushing with lipiodol for unexplained (and endometriosis-related) subfertility by hysterosalpingography: a randomized trial. *Hum Reprod.* 2004 Sep;19(9):2043-51.

³ Johnson NP et al. Lipiodol fertility enhancement: two-year follow-up of a randomized trial suggests a transient benefit in endometriosis, but a sustained benefit in unexplained infertility. *Hum Reprod.* 2007 Nov;22(11):2857-62.

⁴ Wang R et al. Effectiveness on fertility outcome of tubal flushing with different contrast media: systematic review and network meta-analysis. *Ultrasound Obstet Gynecol.* 2019 Aug;54(2):172-181.

⁵ Fang F et al. Oil-based versus water-based contrast for hysterosalpingography in infertile women: a systematic review and meta-analysis of randomized controlled trials. *Fertil Steril.* 2018 Jul 1;110(1):153-160.e3.

⁶ Erratum. *Fertil Steril.* 2019 Jun;111(6):1262.

⁷ NHS. 18/02/2020. www.nhs.uk/conditions/infertility

Press release

- In a meta-analysis of randomized controlled trials: in a group of women who underwent an HSG with Lipiodol® Ultra Fluid, 42% more became pregnant within six months compared to women who received a water-based contrast medium. The overall odds ratio (OR) for pregnancy was significantly in favor of HSG with Lipiodol® Ultra Fluid: OR of 1.42 [1.10; 1.85] when compared to HSG with a water-based contrast medium (6 studies, n=2,598).⁸

“This is great news for UK patients experiencing difficulties conceiving, as it brings them additional hope by enhancing their chances of falling pregnant at an early stage of their fertility journey. As with any procedure patients should be aware of any associated risks”, said Gwenda Burns, Chief Executive of Fertility Network UK.

“Our clinical experience of Lipiodol® Ultra Fluid has showed us that its use is similar to water-based contrast media and does not alter the patient experience during the exam. However, it is noteworthy that long term follow-up studies showed that performing an HSG with Lipiodol® Ultra Fluid reduces the median time to pregnancy by around 4 months, as compared to an HSG with the reference contrast media”, said Prof. Colin Duncan (Royal Infirmary Edinburgh, Chair of the Society for Reproduction & Fertility).⁹

“At Imperial College Healthcare NHS Trust, we have performed more than 10,000 HSGs over the last few decades. The evidence-based results from the H2Oil study encouraged our HSG and fertility teams to use Lipiodol® Ultra Fluid for HSG in selected patients. After several months of use, we can confirm that an HSG with Lipiodol® Ultra Fluid is an exciting and valuable technique in the management of patients being investigated for fertility issues in our centre. Our teams at Imperial College Healthcare NHS Trust will soon to be involved as investigators in on-going randomised controlled clinical trials evaluating the performance of Lipiodol® Ultra Fluid for HSG in extended populations undergoing fertility workup“, said Prof. Anne Hemingway (Imperial College Healthcare NHS Trust, London).

The United Kingdom is the sixth European country to grant approval for HSG in women undergoing infertility workup after Ireland, Hungary, the Netherlands, the Czech Republic and Denmark. Lipiodol® Ultra Fluid is also currently approved for HSG in ten additional countries (USA, including Puerto Rico, Canada, Argentina, Turkey, South-Africa, Japan, Taiwan, Thailand, Australia and New Zealand).

In 2016, the Guerbet Group launched its Women’s Health franchise with the ambition to improve the quality of infertility management and breast cancer surgery (www.guerbet.com/products-solutions/women-s-health/).

About Lipiodol® Ultra Fluid

Lipiodol® Ultra Fluid (ethyl esters of iodized fatty acids of poppyseed oil) is the only oil-based contrast agent indicated for HSG. Lipiodol® Ultra Fluid is indicated for HSG in ten countries (USA, including Puerto Rico, Canada, Argentina, Turkey, South-Africa, Japan, Taiwan, Thailand, Australia and New Zealand). Lipiodol® Ultra Fluid is indicated for HSG in women undergoing infertility workup in the UK, the Czech Republic, Ireland, Hungary, Denmark and the Netherlands.

Lipiodol® Ultra Fluid is available in 47 countries and also approved for other uses in interventional radiology. Indications may vary from country to country, please refer to the local Summary of Product Characteristics.

⁸ Mohiyiddeen L et al. Tubal flushing for subfertility. Cochrane Database Syst Rev. 2020 October 15;(5):CD003718.

⁹ van Rijswijk J et al. Tubal flushing with oil-based or water-based contrast at hysterosalpingography for infertility: long-term reproductive outcomes of a randomized trial. Fertil Steril. 2020 Jul;114(1):155-162.

Press release

About Guerbet

Guerbet is a leader in medical imaging worldwide, offering a wide range of pharmaceutical products, medical devices, digital and AI solutions for diagnostic and interventional imaging, to improve the diagnosis and treatment of patients. A pioneer since more than 90 years in the field of contrast media with over 2,800 people globally, Guerbet is continuously innovating with 9% of revenue dedicated to Research & Development and four centers in France, Israel and the United States. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €817 million in revenue in 2019. For more information about Guerbet, please visit www.guerbet.com.

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