

18-454 Illingworth

5-3-18v1

1

1 Ulipristal Acetate for Treatment of Symptomatic Uterine Leiomyomas: A Randomized 2 Controlled Trial

3

4 We read with interest the randomized controlled trial evaluating ulipristal acetate for the
5 treatment of symptomatic uterine leiomyomas by Simon et al.¹ The authors should be
6 congratulated for undertaking a multicenter randomized trial evaluating the efficacy of
7 ulipristal acetate for the treatment of symptomatic uterine leiomyomas in such a diverse
8 population.

9

10 The authors described a commendable objective to “evaluate the efficacy and tolerability of
11 ulipristal acetate,” however, we wonder if an emphasis on safety would have been beneficial
12 in light of concerns recently expressed by the European Medicines Agency.²

13

14 The European Medicines Agency has recommended no new women should be started on
15 ulipristal acetate after reports of serious liver injury, including liver failure leading to
16 transplantation. They advise all women currently taking ulipristal acetate should have a liver
17 function test at least once every 4 weeks during treatment and repeated 2–4 weeks after
18 stopping treatment. If the test is abnormal, treatment should be stopped, and the women
19 closely monitored.² It would be useful for the authors to clarify their clinical practice
20 recommendations considering the recent European Medicines Agency advice.

21

22 In the near future, regulatory decisions will be informed by systematic reviews of published
23 evidence. Would the authors consider publishing any data related to deranged liver function,
24 hepatitis, liver failure, or liver transplant collected as part of their trial? As any future
25 assumption that they were absent is likely to be correct but may not be secure.³ Moving
26 forward we would advocate for the development of a minimum data set to improve safety
27 reporting in future research, permitting a more balanced assessment by considering the
28 trade-off between the benefits and harms of ulipristal acetate.⁴

18-454 Illingworth
5-3-18v1
2

Financial Disclosure

The authors did not report any potential conflicts of interest.

Mr Benjamin JG Illingworth ¹
Martin Hirsch MRCOG ²
James M. N. Duffy MBChB MRes ³

¹ University College London Medical School, London, WC1E 6BT, United Kingdom

² Queen Mary, University of London, London, E1 2AB, United Kingdom.

³ Balliol College, University of Oxford, Oxford, OX1 3BJ, United Kingdom.

Correspondence to:

Dr James M. N. Duffy MBChB MRes BSc (Hons) PG Cert HCL
Balliol College, University of Oxford, Oxford, OX1 3BJ, United Kingdom.
+447949066806
james.duffy@balliol.ox.ac.uk
@jamesmnduffy

Word count: 273 words

References

¹ Simon JA, Catherino W, Segars JH, Blakesley RE, Chan AP, Sniukiene V, Al-Hendy A.

Ulipristal Acetate for Treatment of Symptomatic Uterine Leiomyomas: A Randomized

Controlled Trial. *Obstet Gynecol* 2018;131(3):431-439.

² Web site: European Medicines Agency. Esmya. Available at:

www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Esmya/human_r

[eferral_prac_000070.jsp&mid=WC0b01ac05805c516f&source=homeMedSearch&category=](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Esmya/human_referral_prac_000070.jsp&mid=WC0b01ac05805c516f&source=homeMedSearch&category=human)

human

Commented [DS1]: AQ: Please provide an update for reference 3. If there isn't one at the time you review your proof, we'll add it to the text, since the journal does not cite in press references in the References list.

18-454 Illingworth

5-3-18v1

3

59 ³Duffy JMN, Hirsch M, Pealing L, Showell M, Khan KS, Ziebland S, McManus RJ.

60 Inadequate safety reporting in pre-eclampsia trials: a systematic evaluation. BJOG; *in press*.

61 ⁴Duffy JMN, Rolph R, Gale C, Hirsch M, Khan KS, Ziebland S, McManus R. Core outcome

62 sets in women's and newborn health: a systematic review. BJOG 2017; 124(10):1481-1489.