FERTILITY AND STERILITY®
VOL. 76, NO. 3, SEPTEMBER 2001

Published by Elsevier Science Inc.
Printed on acid-free paper in U.S.A.

LETTERS TO THE EDITOR

"You'll know it when you see it" statistics

To the editor:

We read with interest the recent article by The North American Ganirelex Study Group (1). However, we were surprised that the results of this large randomized, controlled trial were reported without any comparative statistics. That study is the second such trial comparing the use of ganirelix acetate with that of a GnRH agonist in in vitro fertization (2). One automatically assumes that the conclusions of a randomized study are supported by statistical analysis. However, the title and abstract do not indicate that this paper contains no statistical tests.

Effective reporting of results is an integral part of clinically useful research. The comparative statistical analysis is essential to support the hypothesis of a randomized, controlled trial. However, the authors have performed no comparative statistics in this report. This does not permit the reader to reach any conclusions. Significance tests may sometimes cause misinterpretations of the results, especially when small samples are analyzed or nonparametric tests are used (3). Even in the above situations, these problems can be easily remedied by supplementing these tests with others (3, 4). However, to our knowledge, there is no reason not to perform any comparative statistics.

The authors state that no statistical tests were performed because the aim of the study was to show that ganirelix was not inferior to a GnRH agonist with respect to number of oocytes retrieved and pregnancy rates (1). This conclusion in itself is a statistical statement, and therefore needs statistical analysis.

Finally, the apparent implantation and ongoing pregnancy rates in the ganirelix group are lower compared to those in the GnRH agonist group (1). The authors should perform an appropriate statistical analysis to show the significance of these differences, and also to reach the conclusion they report.

Koray Elter, M.D.
Istanbul, Turkey
February 5, 2001

References

1. Fluker M, Grifo J, Leader A, Levy M, Meldrum D, Muasher SJ, et al. and The North American Ganirelix Study Group. Efficacy and safety of ganirelix acetate versus leuprolide acetate inwomen undergoing controlled ovarian hyperstimulation. Fertil Steril 2001;75:38–45.
2. Borm G, Mannaerts B, and The European Orgalutran Study Group. Treatment with the gonadotrophin-releasing hormone antagonist ganirelix in women undergoing ovarian stimulation with recombinant follicle stimulating hormone is effective, safe and convenient: results of a controlled, randomized, multicentre trial. Hum Reprod 2000;15:1490–8.
3. Simon R. Confidence intervals for reporting results of clinical trials. Ann Intern Med 1986;105:429–35.
4. Young MA. Supplementing tests of statistical significance: variation accounted for. Tutorial. J Speech Hear Res 1993;36:644–56.

PII S0015-0282(01)01945-8

Reply of the authors:

I thank Dr. Elter for his interest in our article (1). He is correct that comparative statistical analyses are not reported in the publication. Like other phase III trials of Antagon (ganirelix acetate; Organon, West Orange, NJ) (2, 3), The North American trial was designed as a noninferiority trial in line with registration requirements for health authorities. This design implies that no comparative statistical analyses are reported. However, based on two-sided confidence intervals of the adjusted treatment difference of the mean, the following statistically significant differences between Antagon and leuprolide acetate treatment are observed: median duration of analogue (−17.2 days), median duration of Follistim (follitropin beta, FSH; Organon) treatment (−1.1 days), total dose of Follistim (−281 IU), mean number of follicles 11 mm at day 6 of stimulation (+2.6 follicles), median estradiol levels at day 6 of stimulation (+346 pg/mL), median estradiol levels at the day of hCG (−701 pg/mL), and the number of oocytes retrieved per attempt (−2.4 oocytes). No differences were observed in terms of the number of good quality embryos or ongoing pregnancy rate.

Keith Gordon, Ph.D.
West Orange, New Jersey
April 11, 2001

References

1. Fluker M, Grifo J, Leader A, Levy M, Meldrum D, Muasher SJ, et al. and The North American Ganirelix Study Group. Efficacy and safety of ganirelix acetate versus leuprolide acetate in women undergoing controlled ovarian hyperstimulation. Fertil Steril 2001;75:38–45.
2. Borm G, Mannaerts B, and The European Orgalutran Study Group. Treatment with the gonadotrophin-releasing hormone antagonist ganirelix in women undergoing ovarian stimulation with recombinant follicle stimulating hormone is effective, safe and convenient: results of a controlled, randomized, multicentre trial. Hum Reprod 2000;15:1490–8.
3. The European and Middle East Orgalutran Study Group. Comparable clinical outcome using the GnRH antagonist ganirelix or a long protocol of the GnRH agonist triptorelin for the prevention of premature LH surges in women undergoing ovarian stimulation. Hum Reprod 2001;16:644–51.

PII S0015-0282(01)01946-X