

# Non-inferiority clinical trial on gonadotropin versus pulsatile gonadotropin-releasing hormone infusion therapy in male adolescent patient with congenital hypogonadotropic hypogonadism

Ying Liu<sup>1#</sup>, Chunxiu Gong<sup>2\*#</sup>, Yaguang Peng<sup>3</sup>

<sup>1</sup>Department of Pharmacy, Beijing Children Hospital, Capital Medical University, National Center for Children's Health, China, 100045;  
<sup>2</sup> Department of Endocrinology, Beijing Children Hospital, Capital Medical University, National Center for Children's Health, China, 100045;  
<sup>3</sup> Center for clinical epidemiology and evidence-based medicine, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, China, 100045

## OBJECTIVES

We investigate the efficacy and safety of non-inferiority clinical trial for human chorionic gonadotropin/ human menopaousal gonadotropin (HCG/HMG) versus pulsatile gonadotropin-releasing hormone (GnRH) which have not been evaluated in puberty boys with CHH. To compare the efficacy and security of two different treatments in male adolescent patient with congenital hypogonadotropic hypogonadism (CHH). To explore the standardization of early treatment and it is possible clinical recommended regimen.

## METHODS

For this prospective cohort nonrandomized controlled study, a total of 43 male adolescent CHH patients were recruited and categorized into HCG/HMG (group 1, n=20) and GnRH (group 2, n=23) groups. All patients were treated for 3-12 months. The study was divided into research period (3 months of treatment) and extension period (3 to 12 months of treatment). Testicular volume (TV), penile length (PL), blood sex hormones levels, height, body weight, and other related laboratory indices were measured and evaluated. And then, when  $\alpha = 0.05$ , take the 3 month growth differential (2ml) between group 1 and group 2 as non-inferior validity boundary value ( $\delta$ ) and conduct independent sample t test. In this study, we observe the therapeutic effect within 3 months and also collect partial extended period data for providing further research experience.

## RESULTS

All CHH patients were treated for over 3 months. At the beginning, the average age of patients, the testicular volume, penile length, penile diameter in group 1 and group 2 were  $15.3 \pm 1.9$  years vs  $14.2 \pm 1.5$  years,  $2.5 \pm 1.4$  ml VS  $2.7 \pm 1.5$  ml,  $4.8 \pm 1.3$  cm VS  $4.2 \pm 1.4$  cm and  $1.6 \pm 0.4$  cm vs  $1.5 \pm 0.4$  cm. The difference of two groups was not statistically significant. After 3 months treatment, the testicular volume, penile length, penile diameter, the growth of testicular volume, the growth of penile length and the growth of penile diameter in group 1 and group 2 were  $4.6 \pm 2.2$  ml VS  $4.6 \pm 2.7$  ml,  $6.1 \pm 1.3$  cm VS  $5.1 \pm 1.6$  cm,  $2.7 \pm 2.7$  ml vs  $2.0 \pm 2.2$  ml,  $1.3 \pm 1.0$  cm vs  $1.0 \pm 0.8$  cm and  $0.9 \pm 0.9$  cm vs  $0.4 \pm 0.4$  cm. The difference of two groups was not statistically significant. There was no significant difference in height, body weight, or BMI between the two treatments. Based on the principles of hypothesis-test, mean value  $M=0.25625$ , standard error (SE) = 0.69319,  $M \pm 1.96, Se = -0.25625 \pm 1.3586524, (-1.161, 1.10)$ . The growth differential of testicular volume between group 1 and group 2 was less than 2ml in ( $P < 0.05$ ). It can be inferred that group 1 is not inferior to group 2. There was no significant difference in efficacy comparison in some of the patients were treated after 6-12 months in both groups. There was no significant difference in side effects in both groups.

## CONCLUSIONS

In this clinical trial, 3 months was an observation period. Short-term therapeutic indicated adolescents patients with CHH were effectively treated with HCG/HMG and GnRH. We discovered that the effect of HCG/HMG was as good as GnRH in treating adolescent boys with CHH. This therapeutic schedule can be used in more patients.

## References

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