Guidance for use of gonadotropin-releasing hormone analogues (GnRHa) to optimise linear growth and final height

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Review date: 2029

The aim of this **guidance** is to support clinicians considering using GnRHa to optimise linear growth and final height outcome in different clinical scenarios by summarising the evidence up to 2025. This is "**guidance**" not a guideline and due to the paucity of studies in this area, evidence-based standards of care cannot be provided. The guidance should be read in conjunction with *"Guidance for use of aromatase inhibitors (AI) to optimise linear growth and final height",* weblink below.

This guidance does not cover the use of GnRHa for:

- Gonadotropin-dependent precocious puberty (GDPP)
- As a monotherapy to improve height
- Gender incongruence

Background

Height may be optimised for selected growth disorders or clinical scenarios by delaying skeletal maturation using a GnRHa or an aromatase inhibitor (AI). Use of GnRHa and AI may allow additional time to promote linear growth by reducing growth plate exposure to oestrogens and delaying epiphyseal fusion. These agents are often used in combination with recombinant human growth hormone (rhGH). The decision to use either GnRHa or AI is individualised. This guidance addresses the use of GnRHa for optimising linear growth.

In the context of normal pubertal timing, the use of GnRHa as an adjunct therapy for optimising linear growth is off-label. Nevertheless, in certain situations, GnRHa may still be offered and is supported by varying levels of evidence.

It is not usually recommended to use GnRHa as a monotherapy (i.e. not in combination with rhGH) to optimise final height in children with normal physiologically timed puberty [1].

There are separate BSPED guidance/clinical standards available for:

- Guidance for use of aromatase inhibitors to optimise linear growth and final height https://www.bsped.org.uk/media/irah0phx/aromatase-inhibitor-guideline-final-280126.pdf
- Shared Care Guidelines: Use of Gonadotrophin Releasing Hormone (GnRH) Agonists https://www.bsped.org.uk/media/1978/gnrh-agonists-shared-care-guidelines-final-version-march-2022.pdf
- Shared care guidelines for GH therapy https://www.bsped.org.uk/media/alxow2wv/gh-shared-care-guidelines-20240206.pdf
- Standards for GH treatment for GHD https://www.bsped.org.uk/media/iczlv32f/clinical-standards-for-gh-treatment-of-ghd-in-childhood-and-adolescence-v1.pdf
- Standards for GH treatment for other growth disorders excluding GHD https://www.bsped.org.uk/media/kfnh1unq/clinical-standards-for-gh-treatment-of-growth-disorders-excluding-ghd-19122023.pdf

Introduction

Other than for gonadotropin-dependent precocious puberty (GDPP), there is limited evidence for the use of GnRHa therapy to optimise linear growth for growth disorders as there are few randomised controlled trials, wide variations in age of treatment initiation, choice of therapy, duration of treatment, and limited adult height data. Although we provide references below to support clinicians in treatment initiation, the overseeing clinician remains responsible for the decision. Larger trials are needed to generate data to support the use of GnRHa for these indications and is currently an unmet need. This emphasises the need to include a risk benefit discussion with the patient and caregivers prior to initiation of therapy.

1. Assessment and investigations prior to the use of GnRHa

- History: onset and tempo of puberty
- Examination: height, weight, BMI, height velocity, pubertal staging, height of parents / mid-parental height (SDS/centile), and target height range
- Investigations:
  - Bone age
  - Basal LH, FSH, oestradiol/testosterone
- Discuss with patient and caregivers:
  - Explanation of off-label use of GnRHa
  - Option of not intervening
  - Evidence base
  - Potential benefits, risks, and efficacy of therapy
  - Acceptability of injections and treatment duration
  - Side effects (See Appendix 1)
  - Potential risks of GnRHa include:
    - Temporary reduced bone mineral density during therapy*
    - Possible negative psychosocial impact of intentionally delaying puberty
    - Potential differences in behaviour and interests compared to peers
    - Causes hypogonadism at a key developmental phase
- Document discussion in the clinical notes

*Typically recovers following cessation of treatment when used for GDPP but currently long-term data are lacking for other indications

2. Contra-indications of GnRHa therapy

Absolute contraindications:

- Undiagnosed vaginal bleeding
- Reached final height
- Allergy to GnRHa or its constituents/excipients

Other contraindications:

- Nearing the end of puberty/pubertal growth as evidenced by:
    - Approaching final or near final height (HV <2cm/yr in the preceding 6 months)
    - Late/adult pubertal stage (Tanner stage ≥4 in boys or breast stage ≥3 in girls)
    - Advanced bone age indicating limited further growth potential
- At a chronological age where delaying puberty further would be considered inappropriate considering the length of treatment course needed and following a risk vs. benefit discussion with the patient and caregiver(s) (see below).

3. Duration of therapy

The minimum advised treatment period will be individualised but is usually **2 years** [2, 3]. Treatment of **3 years or more** has shown increased benefit for some growth disorders [2, 4, 5, 6].

4. Monitoring during GnRHa therapy

- 6 monthly - height, height velocity, weight, BMI, pubertal staging
- Bone age assessment at least annually [7]
- Regular assessment of potential psychological impact
- If poor response, consider increased injection frequency, alternative GnRHa preparation or discontinuation of therapy

5. Treatment discontinuation

Consider discontinuation of GnRHa treatment before or by the age of 13 years in girls and 14 years in boys. In selected cases (e.g. predicted poor height outcome), continuation beyond these ages may be offered following discussion with the patient and caregiver and consideration of potential risks and psychosocial implications. Following discontinuation of GnRHa, clinical monitoring should continue to ensure recommencement and completion of puberty.

6. Use of GnRHa to optimise linear growth in different clinical scenarios

GnRHa therapy is usually offered in combination with rhGH.

A. Growth disorders and use of GnRHa

The use of GnRHa as a monotherapy to improve linear growth is not recommended [1]. However, use of GnRHa in combination with rhGH has been used for selected growth disorders:

i. Growth hormone deficiency (GHD)

In pubertal males and females with GHD, a mean age of 14 years and no previous treatment for GHD, a combination of rhGH and 3 years of GnRHa treatment resulted in a 12.3 cm gain of predicted height compared with 3.3 cm in those treated with GH alone, with near final height improving from -4.0 SDS in both groups to -2.7 SDS in the GH alone vs -1.3 SDS in the combination group [8].

ii. Short stature secondary to being born small for gestational age (SGA)

In short children born SGA, the addition of 2 years of GnRHa to rhGH treatment can be considered if the expected adult height is below -2.5 SDS at the onset of puberty. This strategy can result in a mean increase in adult height of 6.6 cm in boys and girls [3].

iii. Silver-Russell syndrome

Rapidly advancing bone age, adrenarche and early puberty can contribute to poor final height outcome in SRS. Consider personalised treatment with GnRHa (in addition to rhGH) for at least 2 years in children with evidence of central puberty (starting no later than age 12 years in girls and age 13 years in boys) to preserve adult height potential [9, 10].

iv. Temple syndrome

Temple syndrome is characterised by SGA, postnatal growth failure, rapidly advancing bone age and gonadotropin-dependent precocious puberty or early puberty. Limited data shows the addition of GnRHa to rhGH therapy improves height prognosis and should be considered on a case-by-case basis for early puberty or GDPP [11, 12].

v. *SHOX, ACAN* and *NPR2* gene haploinsufficiency

For these conditions evidence is limited. In children with *SHOX* gene defects, increased height (approximately +0.5 SDS) was observed in a small study (n=10) with 2-5 years GnRHa therapy combined with rhGH vs no treatment [13]. For those with *ACAN* defects, a study of 4 patients suggested the addition of GnRHa for 2 years with rhGH can be beneficial [14]. *ACAN* can be associated with advanced bone age with or without precocious puberty, but early puberty is not a feature of the condition [15, 16]. GnRHa may have a modest effect at improving adult height in *NPR2* haploinsufficiency (~ 0.3-0.5 SDS) but insufficient data are currently available [17, 18]

vi. Severe Primary IGF-1 Deficiency (SPIGFD)

Early institution of rhIGF-1 to promote catch-up growth prior to the onset of puberty is the optimal strategy to improve height prognosis in SIGFD. The reported numbers of children treated with combined rhIGF-1 and GnRHa therapy are small and show no overall difference in adult height between patients with or without prior GnRHa exposure [19, 20]. However, many started GnRHa therapy late. Initiating GnRHa treatment earlier (at pubertal onset) in SIGFD patients treated with rhIGF-1 may improve height outcomes but more data are needed [21, 22].

B. Other clinical scenarios where GnRHa may be considered

i. Survivors of childhood malignancy treated with recombinant GH for GHD

There is limited evidence suggesting improved final height in childhood cancer survivors treated with rhGH for GHD in combination with GnRHa [23, 24]. However, GnRHa may have a role for preserving height in those with rapidly progressing puberty following cancer treatment.

ii. Cushing's disease treated with recombinant GH for GHD

GnRHa used in combination with rhGH for GHD may improve height prognosis for those with limited time for catch up growth [25].

iii. Congenital adrenal hyperplasia (21-hydroxylase deficiency)

GnRHa monotherapy may be of benefit to improve adult height in children with 21-OHD CAH who experience early puberty (boys < 10 years, girls < 9.5 y) [26].

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Appendix 1

Adverse Effects

In the initial phase of therapy, a short-term increase of sex hormones occurs, followed by a decrease to values within the pre-pubertal range. Due to this pharmacological effect, adverse events occur more frequently at the beginning of treatment.

Common potential adverse effects include:

- Gastrointestinal: Nausea, gastrointestinal discomfort, vomiting
- Psychological: Depression, mood alteration or emotional lability
- Gynaecological: Metrorrhagia**, vaginal discharge (more common with leuprorelin)
- Other: Headache, skin reactions, anaphylactic reactions (uncommon)

** An initial vaginal bleed following therapy onset is a recognised side effect due to a combination of hormonal surge followed by shedding of any uterine lining. Patients and their families should be warned about this and reassured that it is not an indication for concern or of treatment failure.

A more comprehensive list, including potential side effects of unknown frequency, can be found in the British National Formulary for Children (BNFc) or in the individual preparation literature.

Other considerations

- **Reversible Effects**: Suppression of puberty is fully reversible upon discontinuation of therapy. Earlier bone age at the start or end of GnRHa treatment indicates more time to menarche, with time from end of treatment to menarche typically between 8 to 22 months (mean 15-16 months), however, this can be as early as 2-3 months and as long as 30-60 months in some cases [27, 7]. No variation from general population in regularity of ovarian cycles has been identified [7].
- **Weight Gain**: The weight gain is manageable and not usually associated with a significant change in BMI [28, 7].
- **Bone Health and Density**: A minimal risk of decreased bone density during GnRHa therapy, however subsequent bone mass accrual and peak bone mass do not appear to be negatively affected, with no increase in fractures [7].
- **Psychological Well-being**: Delay in puberty can improve psychosocial outcomes for children who experience early pubertal changes, with combined GH/GnRHa treatment having no long-term negative effects on cognition, health related quality of life (HRQoL), self-perception, and behaviour in early adulthood, compared with GH treatment only [29].
- **Height velocity with GnRHa:** A reduction in height velocity with successive years of GnRH treatment has been documented in CPP [30]. This is thought to be related to reduced GH stimulation and effect [28]. This can be mitigated by concomitant growth hormone therapy, provided a sufficient treatment period is undertaken [31].
- **Fertility outcome:** Follow up studies indicate no impact on fertility for girls or boys [7]. Associations between CPP and PCOS is not clearly understood, though current evidence indicates incidence in treated girls does not exceed that of general population [7]