

SHARED CARE

Drug: LEUPRORELIN

Protocol number: CV 22

Indication: PRECOCIOUS PUBERTY IN CHILDREN

General guidance

This protocol sets out details for the shared care of patients receiving leuprorelin, a GnRH analogue, and should be read in conjunction with the General Guidelines for Shared Care . Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. **The doctor who prescribed the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

Leuprorelin, a gonadotrophin releasing-hormone (GnRH) analogue, is used in paediatric practice for the suppression of precocious puberty (unlicensed indication). It is a synthetic analogue of naturally occurring GnRH which possess greater potency than the natural hormone. Chronic administration results in an inhibition of gonadotrophin production and subsequent suppression of ovarian and testicular steroid production. These effects are reversible on discontinuation of therapy.

Indications for leuprorelin therapy

- a) True precocious puberty due to premature activation of the hypothalamic-pituitary-gonadal axis. This is generally idiopathic, but may occur as a result of intracranial tumours, following radiotherapy, or in association with certain rare syndromes.
- b) In cases where puberty needs to be delayed in order to maximise growth potential in growth hormone deficient children.

Diagnostic criteria for precocious puberty

- a) Girls - Presence of pubic hair and/or breast development before 8 years.
Boys - Presence of pubic hair and/or genital development before 9 years.
- b) Tall stature when related to parental height.
- c) Rapid growth rate.
- d) Advanced skeletal maturation.
- e) Confirmation of the central nature of the precocious puberty by pituitary function tests \pm cranial imaging.

Use of leuprorelin in precocious puberty

Leuprorelin will only be considered when no other treatment is available, and when continuation of puberty in the individual child would lead to either ;

- a compromise of final adult height and/or
- detrimental effects to the child's psychological state.

Responsibilities

Endocrine specialist responsibilities

1. When treatment is **initiated** send Shared Care request form with Shared Care Protocol to GP.
2. Arrange for the first injection to be given by the endocrine clinic specialist nurse.
3. When a GP positive response to SC has been received and patient has been stabilised send a letter to GP “handing over” the Shared Care of the patient to the GP.
4. Review patient's pubertal development, growth and response to treatment at 3 to 6 monthly intervals. Monitoring will include height and weight measurements, pubertal staging, bone age assessment at approximately 12 monthly intervals, and hormone measurements as indicated.
5. Advise the GP on continuing or stopping leuporelin therapy following medical review of the patient and associated drug therapy
6. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

GP responsibilities

1. Within one week of receipt return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Provide family with advice on the need for investigation of the child's precocious puberty.
3. Monitor the general health of the patient.
4. Prescribe leuporelin as part of a shared care agreement.
5. Arrange that someone from the practice will be available to administer the second and subsequent injections.
6. Report adverse effects of therapy to specialist or deputy and the Medicines and Health Care products Regulatory Agency (MHRA).
7. To act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

C. Patient (and/or carer) responsibilities

1. Consent to treatment with leuporelin.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst receiving leuporelin

Dosage Regimen

Leuporelin, slow release ("Prostap SR")

A depot formulation, administered as a single subcutaneous or intramuscular injection every month. The dose is usually 3.75 mg. Each vial contains 3.75 mg Leuporelin acetate as a powder, which is reconstituted with a pre-filled syringe containing 1ml of diluent. No other fluid should be used to reconstitute the powder. (Cost: Children's BNF 2006 £125.40 per 3.75mg dose). Alternatively

Prostap 3 (11.25mg) appear to provide adequate pubertal suppression given every 10-12 weeks.

Monitoring

Monitoring will all be provided by the Consultant Paediatric Endocrinologist and involves 3-6 monthly outpatient reviews for measurement of growth and pubertal status and where necessary biochemical testing of the pituitary gonadal axis. Once started, treatment will generally be continued until an age when puberty can be allowed to recommence. This will vary with each child, but will tend to be at around 10 -11 years of age.

Adverse effects

There is little safety and efficacy data in children since their use in this age-group is uncommon. However, all of the side-effects which have been documented in adults are a result of the suppressive effect on the gonadal axis, and these are the effects which are desired in these children. Vaginal bleeding and discharge can occur following the 1st injection. Nausea and vomiting is described.

Interactions

No significant interactions are recognised.

Special recommendations

No special recommendation is required

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