

Scott & White Hospital & Clinics

Clinical Research at Scott & White

Study Title: An Open-label Non-comparative, Multi-Center Study to Assess The Efficacy and Safety of Bicalutamide When used in Combination With Anastrozole For the Treatment of Gonadotropin-independent Precocious Puberty in Boys with Testotoxicosis

Project ID#: 8815

Department: Pediatric-Endocrinology

Sponsor: AstraZeneca Pharmaceuticals

Brief Synopsis of the Study

Condition(s):	Treatment(s):
Testotoxicosis is a condition that causes early puberty in boys including growth in height, and early development of bigger muscles, body hair and enlargement of the sexual organs	This study is being carried out to see if a combination of two pediatric formulated medicines, Bicalutamide and Anastrozole, given daily over a 12 month period of time, is effective in treating testotoxicosis.

Who is eligible to participate in the study?

Age: 2 years and older

Gender: Male

Inclusion Criteria:

- 1) Diagnosed with testotoxicosis based on early puberty shown by increased growth in height, early development of bigger muscles, body hair, enlargement of penis and testicles, possibly with increased aggression and acne.
- 2) Significantly advanced bone age (defined as bone age of at least 12 months beyond chronological age).
- 3) Have received no previous treatment with any anti-androgen (drugs which lowers the male sex hormone).

Exclusion Criteria:

- 1) Central precocious puberty confirmed by blood test known as a GnRH stimulation test.
- 2) Liver and kidney tests not more than 1.5 times the upper limit of normal for age.
- 3) Participation in a clinical study at time of enrollment.
- 4) Known hypersensitivity to any of the study medications.
- 5) A medical condition that in the opinion of the physician exposes a subject to an unacceptable level of safety risk or that affects subject compliance.

What may be involved/required for subject participation? (Visits, tests and/or logs, etc.)

The study may involve up to 23 visits over the initial 12 months, followed by annual follow-up visits until final adult height is achieved. Some of the visits involve blood tests, x-rays, and physical examinations.

For More Information Contact:

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