
CLINICAL TRIAL PROTOCOL

Name of Trial

An open-label non-comparative, multi-centre study to assess the efficacy and safety of bicalutamide* when used in combination with anastrozole* for the treatment of gonadotrophin-independent precocious puberty in boys with testotoxicosis (*not licensed for use in this condition)

Inclusion criteria

Boys \geq 2 years

Naïve to anti-androgen therapy (N.B. ketoconazole and spironolactone are considered acceptable, as is prior use of anastrozole or other aromatase inhibitors)

Exclusion criteria

Evidence of central precocious puberty (based on GnRH stimulation test)

Liver function $>$ 1.5x upper limit

Name of the drug(s)* or product(s) concerned by the trial:

Bicalutamide – orodispersible tablet at 12.5mg and 25mg. Dose titrated per individual to either 12.5, 25, 50, 100 or 150mg daily.

Anastrozole – orodispersible tablet at 0.5mg and 1mg. Dose titrated per individual to either 0.5, 1, 2, 4 or 8mg daily.

Date of the start of the trial:

22/11/04

Duration scheduled:

2 years initial recruitment period, 12 month treatment period and follow up until final adult height achieved.

Number of individuals to be included:

20 (CLOSED TO RECRUITMENT)

Phases of the trial:

Phase 2

Single centre trial
National multi-centre trial
International multi-centre trial