

Protocol for a multicentre audit of age at surgery and outcomes following unilateral orchidopexy for palpable testis

Abstract: In September 2011 the British Association of Paediatric Urologists wrote a consensus statement including the recommendation that orchidopexy should be performed from as early as 3 months of age although between 6 and 12 months is acceptable. However it is not known whether operating at earlier age may affect the rate of testicular atrophy following orchidopexy. It is also not known whether current referral patterns would permit such early intervention.

Aim: To establish current practice with regards to the age at orchidopexy in the UK in a multicentre national audit and determine the testicular atrophy rate post surgery at 6 to 12 months follow-up.

Endpoints:

- 1) Rate of testicular atrophy
- 2) Rate of re-operation/ testicular ascent
- 3) Wound infection rates
- 4) Anaesthetic complications/ overnight stays

Hypothesis: Reducing the age at orchidopexy may affect the rate of testicular atrophy post orchidopexy.

Standards: Currently accepted rate of atrophy is 5% for single stage orchidopexies.

(1)

Sample Size Calculation:

1) Aiming to detect an increase in atrophy to 10%. Power 0.8, alpha 0.05

n= 185 in each group

Groups:

1. Age at orchidopexy < 1yr
2. Age at orchidopexy >1 yr

(to detect difference to 8% sample size would be 478 in each arm)

Methods: The audit will be performed over a 3 month period. Participation from at least 10 paediatric surgical centres and 20 district general hospitals performing general surgery of childhood is estimated to recruit 400 patients. The audit will be performed using a standardised pre-determined protocol and a database. The audit standards are taken from published literature including: <5% atrophy rate post orchidopexy, < 2% testicular ascent requiring re-operation, < 2% wound infection rate, <2% overnight stay following planned daycase surgery. The audit report will be prepared in accordance to guidelines set by the STROBE statement for observational studies.

Potential Bias: Adult surgeons/ urologists with an interest in general surgery of childhood may not operate on small infants due to anaesthetic considerations in

district general hospitals therefore those operated at a younger age may be more likely to be performed by paediatric surgeons.