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Summary attachment - study ended before 21 July 2013

EudraCT number: 2007-002655-16

Full title of the study: Androgen metabolism and doping tests

Sponsor: Karolinska Institutet

Contact person: anders.rane@ki.se

Study ended: 2007-06-30

Link to published article: https://pubmed.ncbi.nlm.nih.gov/18334593/

Abstract from published article:
Context: Testosterone abuse is conventionally assessed by the urinary testosterone/epitestosterone (T/E) ratio, levels above 4.0 being considered suspicious. The large variation in testosterone glucuronide (TG) excretion and its strong association with a deletion polymorphism in the uridine diphospho-glucuronosyl transferase (UGT) 2B17 gene challenge the accuracy of the T/E ratio test.
Objective: Our objective was to investigate whether genotype-based cutoff values will improve the sensitivity and specificity of the test.
Design: This was an open three-armed comparative study.
Participants: A total of 55 healthy male volunteers with either two, one, or no allele [insertion/insertion, insertion/deletion, or deletion/deletion (del/del)] of the UGT2B17 gene was included in the study.
Intervention: A single im dose of 500 mg testosterone enanthate was administered.
Main outcome measures: Urinary excretion of TG after dose and the T/E ratio during 15 d were calculated.
Results: The degree and rate of increase in the TG excretion rate were highly dependent on the UGT2B17 genotype with a 20-fold higher average maximum increase in the insertion/insertion group compared with the del/del group. Of the del/del subjects, 40% never reached the T/E ratio of 4.0 on any of the 15 d after the dose. When differentiated cutoff levels for the del/del (1.0) and the other genotypes (6.0) were applied, the sensitivity increased substantially for the del/del group, and false positives in the other genotypes were eliminated.
Conclusions: Consideration of the genetic variation in disposition of androgens will improve the sensitivity and specificity of the testosterone doping test. This is of interest not only for combating androgen doping in sports, but also for detecting and preventing androgen abuse in society.

Sofie Possmark
Coordinator
Compliance & Data Office
Research Support Office
Karolinska Institutet
Sweden