Subject: Metaanalyse zur Qualität von 34 klinischen Studien (Finasterid) Posted by Pandemonium on Mon, 13 Apr 2015 18:53:01 GMT

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Adverse Event Reporting in Clinical Trials of Finasteride for Androgenic Alopecia A Meta-analysis

http://archderm.jamanetwork.com/article.aspx?articleid=2212246

Zitat:Results Of 34 clinical trials, none had adequate safety reporting, 19 were partially adequate, 12 were inadequate, and 3 reported no adverse events. Funnel plots were asymmetric with a bias toward lower odds ratio for sexual adverse effects, suggesting systematic underdetection. No reports assessed adequacy of blinding, 18 (53%) disclosed conflicts of interest, and 19 (56%) received funding from the manufacturer. Duration of drug safety evaluation was 1 year or less for 26 of 34 trials (76%). Of 5704 men in the clinical data repository who were treated for AGA with finasteride, 1.25 mg/d or less, for AGA, only 31% met inclusion criteria for the pivotal trials referenced in the manufacturer's full prescribing information and 33% took finasteride for more than 1 year.

Conclusions and Relevance Available toxicity information from clinical trials of finasteride in men with AGA is very limited, is of poor quality, and seems to be systematically biased. In a cohort of men prescribed finasteride for routine treatment of AGA, most would have been excluded from the pivotal studies that supported US Food and Drug Administration approval for AGA. Published reports of clinical trials provide insufficient information to establish the safety profile for finasteride in the treatment of AGA.

Metaanalyse vom 1. April, vorhin im englischen Wikipedia-Artikel zu Finasterid gefunden.

Meinungen?