Wiener Biometrische Sektion
der Internationalen Biometrischen Gesellschaft
Region Österreich – Schweiz

http://www.meduniwien.ac.at/wbs/

Einladung zum

Biometrischen Kolloquium

am Dienstag den 23.01.07 um 15:00 Uhr

im Seminarraum (3.Stock, Raum 88.03.513) der
Besonderen Einrichtung für Medizinische Statistik und Informatik
(MSI) der Medizinischen Universität Wien
Spitalgasse 23, 1090 Wien

Es werden zwei Vorträge stattfinden:

Nigel Stallard (Warwick Medical School, The University of Warwick, UK):

A group-sequential method for clinical trials with treatment selection

Tim Friede (Warwick Medical School, University of Warwick):

Blinded sample size reestimation in non-inferiority trials with binary endpoints

Wir ersuchen um zahlreichen Besuch dieser Doppelveranstaltung,

Werner Brannath
Präsident

Thomas Lang
Sekretär

Abstracts:

Nigel Stallard: A group-sequential method for clinical trials with treatment selection

Most statistical methodology for phase III clinical trials focuses on the comparison of a single experimental treatment with a control treatment. Recently, however, there has been increasing interest in methods for trials that combine the definitive analysis associated with phase III clinical trials with the treatment selection element of a phase II clinical trial.

This talk will describe a group-sequential method for combining phases II and III. Using this approach, the phase II/III clinical trial proceeds in stages. The first stage is rather like the usual phase II trial, with patients randomised between a control treatment and a number of experimental treatments. At the end of this stage, the best experimental treatment is selected. If this is clearly superior or clearly inferior to the control treatment, the trial might be stopped at this point either for efficacy or for futility respectively. If the trial is not stopped, it continues to the second stage, which is more like the usual phase III trial, with recruitment to the control arm and the selected experimental treatment arm alone. The second stage may itself include interim analyses comparing the two treatments.

The talk will conclude with a discussion of the problem of estimation of treatment effects after a trial in which treatment selection has taken place

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Tim Friede: Blinded sample size reestimation in non-inferiority trials with binary endpoints

Joint work with Charles Mitchell (ETH Zuerich) and Guenther Mueller-Velten (Novartis, Basel)

Summary
Sample size calculations in the planning of clinical trials depend on good estimates of the model parameters involved. When the estimates of these parameters have a high degree of uncertainty attached to them, it is advantageous to reestimate the sample size after an internal pilot study. For non-inferiority trials with binary outcome we compare the performance of Type I error rate and power between fixed-size designs and designs with sample size reestimation. The latter design shows itself to be effective in correcting sample size and power of the tests when misspecification of nuisance parameters occurs with the former design.