

Workshops in Medical Research Methodology

The randomised clinical trial – are there alternatives?

(Organisers: Center-head Karin Friis Bach, GCP Unit,
University Hospitals of the Copenhagen Region and Thomas Mandrup-
Poulsen, Center for Medical Research Methodology, Faculty of Health and
Medical Sciences.)



February 23, 2012, 14.00-17.00

Auditorium 1, Bispebjerg Hospital
Uddannelsescentret, indg.50
Tuborgvej 235, 2400 Kbh. NV

Patient cohorts even with common diseases are a limited resource, and increasing costs for randomised clinical trials in phase IIB and III restrict drug development. The problems even expand to phase IV trials at the hospitals, where increasing demands for systematic research in order to improve treatment practice lead to other ways of thinking. Furthermore the rapidly growing concept of personalized health care is conflicting with the very idea of studying cohorts in RCTs

But are there alternatives to the randomised clinical trial? Can adaptive study designs be more widely used without jeopardising blinding and statistical power? Should biological markers be the future keystone when creating evidence? And are the regulatory requirements for drug approval appropriate in 2012? These topics will be presented and discussed.

Participation in the workshop is free and everybody is welcome.

Registration to secretary Bente Kjær (Bente.Kjaer2@regionh.dk) at monday 20th Feb. the latest.

25 JANUARY 2012

**ENDOCRINOLOGY RESEARCH
SECTION**

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Programme

14.00-14.10: Introduction: the RCT under pressure

*Thomas Mandrup-Poulsen, Professor, Core Unit for Medical Research
Methodology, University of Copenhagen*

14.10-14.55: Does Personalized Health Care require new kinds of evidence?

Birgitte Sogaard, Divisional Director, Clinical & Quantitative Pharmacology, Lundbeck A/S

14.55-15.40: Alternatives to the RCT in pediatric oncology

Kjeld Schmiegelow, professor, University of Copenhagen

15.40-16.10: Coffee/tea

16.10- 16.55: Regulatory requirements for RCT evidence – time for adjustment?

Jens Heisterberg, chief physician, Danish Medicines Agency

17.00: Closure

Yours sincerely,

Karin Friis Bach
Centerhead, MSc.Pharm.

Thomas Mandrup-Poulsen
Professor, MD, DMSc