大阪医学統計学セミナー 第99回

Osaka Biostatistics Seminar

6月20日（金）
16：00～18：00

「 Event-Driven Type Design for Clinical Trials with Recurrent Events」

Speaker : Zhang Jingwen
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Abstract: It is common practice in randomized clinical trials with the standard survival outcome to follow patients until a prespecified number of events have been observed, which are called event-driven trials. The event-driven design ensures the target power for a specified type 1 error rate to detect the target hazard ratio, regardless of the specification of other quantities. In recent years, analysis of recurrent events has become popular in randomized controlled trials, especially large-scale confirmatory trials to understand the treatment effect for some chronic conditions. In the absence of the within-subject correlation among multiple events, a similar event-driven design can be taken for the recurrent event outcomes. On the other hand, in the presence of such correlation, one needs to model the correlation among recurrent events in evaluating power and setting the sample size. However, information useful in modeling the within-subject correlation is limited at the design stage. Failing to consider the correlation properly may lead to underpowered studies or unnecessarily long follow-up durations. We propose an event-driven type design for recurrent event outcomes. Our method ensures the target power for the target treatment effect, regardless of the specification of other quantities, by monitoring the robust variance under the marginal rates/means model in a blinded manner.
We investigate the operating characteristics of the proposed monitoring procedure in simulation studies. Furthermore, we illustrate the proposed method using a real clinical trial dataset.

場所：
医学系研究科基礎研究棟L階
医学統計学研究室
オンライン開催

参加ご希望の方は、前日までに下記メールアドレスまでご連絡をお願いいたします。

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