

Data Monitoring in Clinical Trials

A Case Studies Approach

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3. [Data Monitoring for the Aspirin Component of the Physicians' Health Study: Issues in Early Termination for a Major Secondary Endpoint](#)

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Follow-up study: Cook, Cole, Hennekens used MSM to consider non-fatal MI as mediator of CV death.

<https://academic-oup-com.ucsf.idm.oclc.org/aje/article/155/11/1045/57280>

Follow-up study: Meta-analysis of American (Physician's Health) & British (British Doctors) studies

[10.1056/NEJM198804073181412](https://doi.org/10.1056/NEJM198804073181412)

Note: In contrast with multiple other studies, the British Doctors Study showed no effect of aspirin (67% to 500 mg effervescent pill with option to switch to 300 mg coated pill, 33% to no pill; not blinded) on nonfatal MI. Could poor adherence on aspirin arm (Table 2: 24.8%) and/or use of aspirin on no-use arm (9.2%) explain this discordance?

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