Early treatment with aspirin plus extended-release dipyridamole for transient ischaemic attack or
ischaemic stroke within 24 h of symptom onset (EARLY trial): a randomised, open-label, blinded-endpoint trial.

Abstract:
Little is known about the best antiplatelet treatment immediately after ischaemic stroke or transient ischaemic attack (TIA). The EARLY trial aimed to compare outcome in patients given aspirin plus extended-release dipyridamole twice daily either within 24 h of stroke or TIA or after 7 days of aspirin monotherapy. In 46 stroke units in Germany, patients aged 18 years or more who presented with symptoms of an acute ischaemic stroke that caused a measurable neurological deficit (National Institutes of Health stroke scale score ≤ 20) were randomly assigned to receive 25 mg aspirin plus 200 mg extended-release dipyridamole open-label twice daily or 100 mg aspirin monotherapy open-label once daily for 7 days. Patients were randomised by use of a pseudorandom number generator. All patients were then given open-label aspirin plus extended-release dipyridamole for up to 90 days. The primary endpoint was modified Rankin scale score as recorded by centralised, blinded assessment by telephone (tele-mRS) at 90 days. Vascular adverse events (non-fatal stroke, TIA, non-fatal myocardial infarction, and major bleeding complications) and mortality were assessed in a composite safety and efficacy endpoint. Patients were analysed as treated. This trial is registered, number NCT00562588. Between July, 2007, and February, 2009, 543 patients were treated: 283 received early aspirin plus extended-release dipyridamole and 260 received aspirin plus extended-release dipyridamole after 7 days on aspirin. At day 90, 154 (56%) patients in the aspirin plus early extended-release dipyridamole group and 133 (52%) in the aspirin plus later extended-release dipyridamole group had no or mild disability (tele-mRS 0 or 1; difference 4.1%, 95% CI -4.5 to 12.6, p=0.45). 28 patients in the early initiation group and 38 in the late initiation group reached the composite endpoint (hazard ratio 0.73, 95% CI 0.44-1.19 p=0.20). Early initiation of aspirin plus extended-release dipyridamole within 24 h of stroke onset is likely to be as safe and effective in preventing disability as is later initiation after 7 days. Boehringer Ingelheim.