

## Summary attachment - study ended before 21 July 2013

**EudraCT number:** 2007-003186-40

**Full title of the study:** Evaluation of antiplatelet effects of different dosages of aspirin in type 2 diabetic patients.

**Sponsor:** Karolinska Institutet

**Contact person:** [paul.hjemdahl@ki.se](mailto:paul.hjemdahl@ki.se)

**Study ended:** 2010-10-06

**Link to published article:** <https://pubmed.ncbi.nlm.nih.gov/21800009/>

### Abstract from published article:

The efficacy of low-dose aspirin in type 2 diabetes mellitus (T2DM) has been questioned. We tested if twice daily dosing of aspirin would be more effective in T2DM, possibly due to increased platelet turnover. A randomised cross-over study compared 75 mg aspirin OD, 75 mg BID and 320 mg OD ( $\geq 2$  week treatment periods) in 25 patients with T2DM and micro- or macrovascular complications. Platelet responses were examined by impedance aggregometry (WBA) and the IMPACT-R aspirin test in whole blood, light transmittance aggregometry in platelet-rich plasma (LTA), and urinary 11-dehydro-thromboxane B2 (TxM). Aspirin 75 mg BID decreased arachidonic acid (AA)-induced WBA compared to 75 mg OD ( $9.7 \pm 4.5$  vs.  $12.6 \pm 3.5$  ohm;  $p = 0.003$ ) or to 320 mg OD ( $11.5 \pm 4.2$  Ohms;  $p = 0.049$ ). WBA responses to collagen were similarly attenuated by BID or high dosing (by 12-14%;  $p = 0.02$  for both). The IMPACT-R showed a better response to 75 mg BID compared to 75 mg OD ( $p = 0.049$ ), but not to 320 mg OD. AA-induced aggregation by LTA was  $<6.5\%$  on all occasions, with no differences between aspirin dosages. TxM was reduced after 320 mg OD ( $p = 0.002$ ), but not 75 mg BID ( $p = 0.07$ ). Reticulated platelets were highly correlated with mean platelet volume (MPV;  $r_2 = 0.74$ ,  $p < 0.0001$ ). Both markers for platelet turnover were correlated with AA-induced WBA, but neither identified patients who benefited from BID dosing dependably. In conclusion, twice daily dosing improved laboratory responses to aspirin in high risk T2DM patients. Studies of whether BID dosing of aspirin can improve clinical outcomes in such patients are of interest.

**Registered in ClinicalTrials.gov:** NCT00812032

Sofie Possmark  
Coordinator  
Compliance & Data Office  
Research Support Office  
Karolinska Institutet  
Sweden