Table 2. CONSORT diagram

431 patients were included between September, 2005 to January 2008 and underwent randomisation

217 assigned to Placebo group
217 received Placebo as allocated
15 patients were non evaluable
15 questionnaires not received
202 included in primary endpoint analysis per ITT

214 assigned to Cocculine group
213 received Cocculine as allocated
1 received Placebo (dispensation mistake)
13 patients were non evaluable
13 questionnaires not received
201 included in primary endpoint analysis per ITT