

Title: A single-centre, randomised, 2 way crossover, double blind, placebo controlled study in healthy volunteers, to characterise the antacid activity of Gaviscon Double Action Mint Liquid in the fasted state, using a novel intragastric and oesophageal pH catheter

EudraCT number: 2012-004131-23

Sponsor's protocol number: GA1212

The above clinical trial was terminated early; the justification is provided overleaf in Annex I.

Annex I:

D.2.2.1 The justification for early termination of the trial;

This clinical trial application was submitted in order to carry out a pivotal clinical trial based on the results of the pilot trial GA1109. As a result of the serious breach first notified to the MHRA 25th November 2013 (reference GCP-13-062) on the pilot trial GA1109, and subsequent changes to the interpretation of the results, as detailed in the submitted study report addendum, the sponsor Reckitt Benckiser Healthcare (UK) Ltd have decided not to progress with the pivotal trial at this time and therefore confirm that the trial GA1212 will not commence.

As patient recruitment has not been initiated, there are no patient implications in withdrawing this trial.

D.2.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;

No patients as the trial will not commence.

D.2.2.3 The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.

No evaluation of results will take place as the trial will not commence.