

Ondansetron for irritable bowel syndrome with diarrhoea: randomised controlled trial

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Plain language summary

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Background

Irritable bowel syndrome with diarrhoea is characterised by frequent, loose, or watery bowel movements with marked reduction of quality of life. A previous small study suggested ondansetron benefits patients with irritable bowel syndrome with diarrhoea.

Methods

A clinical trial aiming to recruit 400 patients meeting established criteria for irritable bowel syndrome with diarrhoea from 18 centres throughout the UK. Patients received either ondansetron or placebo for 12 weeks but neither the investigator and nor patient could tell which they were receiving. They recorded their worst abdominal pain, stool frequency and consistency daily. The main end point was the proportion of patients meeting a standard recommended by the U.S. Food and Drug Administration (FDA). Being called a “FDA responder” meant they showed reductions to both pain and days with loose bowel movements. Other less important end points included pain intensity, stool consistency and frequency. We also measured the time for content to pass through the gut (whole gut transit time).

Results

The study closed early due to slow recruitment with 80 patients randomised. There were 40.5% of responders in the ondansetron group and 27.9% in the placebo group; however, due to low numbers these differences could be due to chance. Ondansetron produced a significant improvement in average stool consistency in the final month of treatment. Ondansetron slowed whole gut transit time which increased from baseline to 12 weeks by a mean of 3.8 hours, while it fell 2.2 hours on placebo, a difference unlikely to be due to chance.

Conclusion

These results are consistent with previous studies showing that ondansetron improves stool consistency and slows transit. However, because the numbers recruited were smaller than planned, the apparent improvement in “FDA responder” rate could have been due to chance. A further larger trial is needed to confirm the benefit of ondansetron which should be done in primary care where most patients are to be found.

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