University Hospitals Dorset
NHS Foundation Trust

Summary of Results

Study Title:	A single-centre randomised controlled study of Entonox versus midazolam in upper GI
REC Reference:	12/LO/0886
IRAS number:	101675
EudraCT number:	2012-002242-20
Chief Investigator:	Dr Simon McLaughlin
Sponsor:	The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust (now University Hospitals Dorset NHS Foundation Trust)

This clinical trial of an Investigational Medicinal Product began at the Royal Bournemouth Hospital in February 2013. The aim of the trial was to determine whether Entonox (gas and air) is at least as good as intravenous midazolam in providing analgesia and sedation during gastroscopy. It was a randomised controlled trial with a 1:1 randomisation to Entonox plus pharyngeal anaesthesia or Midazolam plus pharyngeal anaesthesia for patients undergoing a diagnostic gastroscopy.

The initial recruitment target was 200 participants and the estimated trial duration was 6 months. Significant challenges occurred with recruitment into the study and despite extending recruitment several times the target was never reached. The final recruitment total was 66 participants and therefore without the statistical power to answer the study objectives.

Recruitment into the study was much more difficult than anticipated with many potential participants wanting to guarantee either no sedation if they wished to drive home themselves or wanting to guarantee sedation. There was a pause in the study due to staffing absence for a significant period, followed by a pause due to the COVID-19 pandemic. Increased infection control prevention measures following the COVID-19 pandemic along with increased waiting lists in endoscopy meant that study clinics were difficult to run following reopening in 2021. Therefore, the decision was made to terminate the study on 28th February 2022 without results and the regulatory authorities were notified.