Search strategies for clinicaltrials.gov

Barrett’s esophagus OR Barrett’s epithelium OR Barrett’s Oesophagus OR Esophageal intestinal metaplasia | Adult, Older Adult

Gastroesophageal Reflux OR gerd | Adult, Older Adult

Nausea OR vomiting | Adult, Older Adult

Chronic Diarrhea | Adult, Older Adult

Gastritis | Adult, Older Adult

Chronic constipation | Adult, Older Adult

Diverticulitis | Adult, Older Adult

Colorectal Cancer Prevention OR colorectal polyps OR colorectal adenomas OR colorectal sessile | Adult, Older Adult

GastroIntestinal Bleeding OR Gastrointestinal Hemorrhage OR Hemorrhages OR GI bleeding | Adult, Older Adult

Ulcerative Colitis OR crohn's disease | Adult, Older Adult

Esophageal Stricture OR esophageal dysphagia | Adult, Older Adult

Irritable Bowel Syndrome | Adult, Older Adult

Celiac Disease OR Celiac and Disorders | Adult, Older Adult

Data fields provided by clinicaltrials.gov

NCT number, trial title, trial status, availability of results on clinicaltrials.gov, study type and design, type of intervention and phase for intervention-based studies, funding source, start date, completion date, date of first reporting of results and location (single- vs. multi-center) of the study.

Additional Data fields abstracted from trials with results available on clinicaltrials.gov on in the form of a publication

Initial publication type (abstract vs. article), date of first publication, study endpoints (clinical vs non-clinical), whether any primary endpoint was met for the study (statistical significance reached as defined in study methodology) and reason for termination for trials with terminated or suspended status. Registered trials for which a publication could not be found were searched by two additional authors (SG and AJT) to ensure a true negative result.

Definitions

A clinical trial was defined as any trial or study that was registered with clinicaltrials.gov. Trial results were treated as available when the results were reported to clinicaltrials.gov or in the form of a publication. A positive trial was defined as a trial that had available results and at least one of the stated primary end point was met. Publication was defined as the first abstract or article published in a peer-reviewed journal that was 1) consistent with the study’s title and aim(s) and 2) conducted by the listed investigator(s) at the listed site(s).

Observational trials were defined by clinicaltrials.gov as studies in which participants were identified as belonging to study groups and were assessed for biomedical or health outcomes. Interventional trials were defined by clinicaltrials.gov as studies in which participants were assigned to groups that receive one or more intervention or no intervention. Interventions were classified into Biologic, Device, Drug and Procedures based on the data obtained from clinicaltrials.gov. All the other interventions were grouped as other miscellaneous interventions. Trial phase was obtained from clinicatrials.gov. If the phase was not listed or was not applicable (e.g. for observational trials) it was classified under not known or not applicable. Reason for termination data was abstracted from clinicaltrials.gov for all the terminated trials. These were classified into 1). Enrolment issues, 2.) Safety concern, adverse events, 3) Medical futility or lack of efficacy, and 4.) Issues related to funding, personnel, supplies, local or federal regulation. Missing and unclear reasons for termination were classified as unclear. Funding sources were classified as 1) NIH or Federal or 2) Industry if the trial was partially or completely funded by NIH or U.S. Federal grant, or by Industry, respectively. If the funding source was listed as other on clinicaltrials.gov then it was treated as such. Clinical endpoints were defined as outcomes directly related to patients (e.g. mortality, hospital-admission, adverse events etc.). Non-clinical end-points were defined as all the other outcomes (e.g. change in laboratory or endoscopic measures). Trial duration was defined as days between start and completion date of trial listed on clinicaltrials.gov.