



## Clinical Study

## No publication bias in industry funded clinical trials of degenerative diseases of the spine

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## ABSTRACT

Industry sponsorship of clinical research of degenerative diseases of the spine has been associated with excessive positive published results as compared to research carried out without industry funding. We sought the rates of publication of clinical trials of degenerative diseases of the spine based on funding source as a possible explanation for this phenomenon. We reviewed all clinical trials registered at [clinicaltrials.gov](http://clinicaltrials.gov) relating to degenerative diseases of the spine as categorized under six medical subject heading terms (spinal stenosis, spondylolisthesis, spondylolysis, spondylosis, failed back surgery syndrome, intervertebral disc degeneration) and with statuses of completed or terminated. These collected studies were categorized as having, or not having, industry funding. Published results for these studies were then sought within the [clinicaltrials.gov](http://clinicaltrials.gov) database itself, PubMed and Google Scholar. One hundred sixty-one clinical trials met these criteria. One hundred nineteen of these trials had industry funding and 42 did not. Of those with industry funding, 45 (37.8%) had identifiable results. Of those without industry funding, 17 (40.5%) had identifiable results. There was no difference in the rates of publication of results from clinical trials of degenerative diseases of the spine no matter the funding source.

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## 1. Introduction

Industry support of medical research represents a substantial source of funding for such and investment on the part of industry [1]. Previous work has demonstrated a propensity for positive outcomes in publications of industry funded medical research as compared to research performed without industry funding, including research into diseases of the spine [1–7]. Reasons for excessive positive results amongst industry funded medical research may include investigator bias in the study performance, inappropriate study designs, fraudulent manipulation of the data or a publication bias [8,9].

Since 2005 the International Committee of Medical Journal Editors has required clinical trials to be registered prospectively in any of a number of public databases for such studies to be considered for publication in a member journal [10]. Similar requirements for phase II–IV clinical trials came under force of law in the USA in 2007 [11]. The largest of these public databases is maintained by the USA National Institutes of Health at <http://www.clinicaltrials.gov>. This public database contains more than

170,000 registered clinical trials at all phases. Despite its sponsorship it is not geographically restricted to clinical trials taking place within the USA. The database contains a number of important data points for researchers including trial phase, number of enrollees, current status, funding sources, as well as the optional ability for researchers to submit results to the database.

The requirement for clinical trial registration in databases allows the comparison of trials for which results are available, either through the peer reviewed publication process and/or within a database itself, versus trials for which results are not available. As such it allows for an analysis of potential publication bias by looking at the rates of available results by funding source. Publication bias, leading to the selective non-presentation of some clinical trial data, may manifest as a belief of excessive efficacy for certain interventions amongst medical professionals and complicate the implementation of evidence based medicine [12–14]. Therefore it is important to look for such a phenomenon as a possible explanation for excessive positive results amongst industry funded clinical trials of degenerative diseases of the spine. To our knowledge no previous study has sought evidence for or against publication bias in clinical trials of degenerative spinal disease.

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## 2. Methods

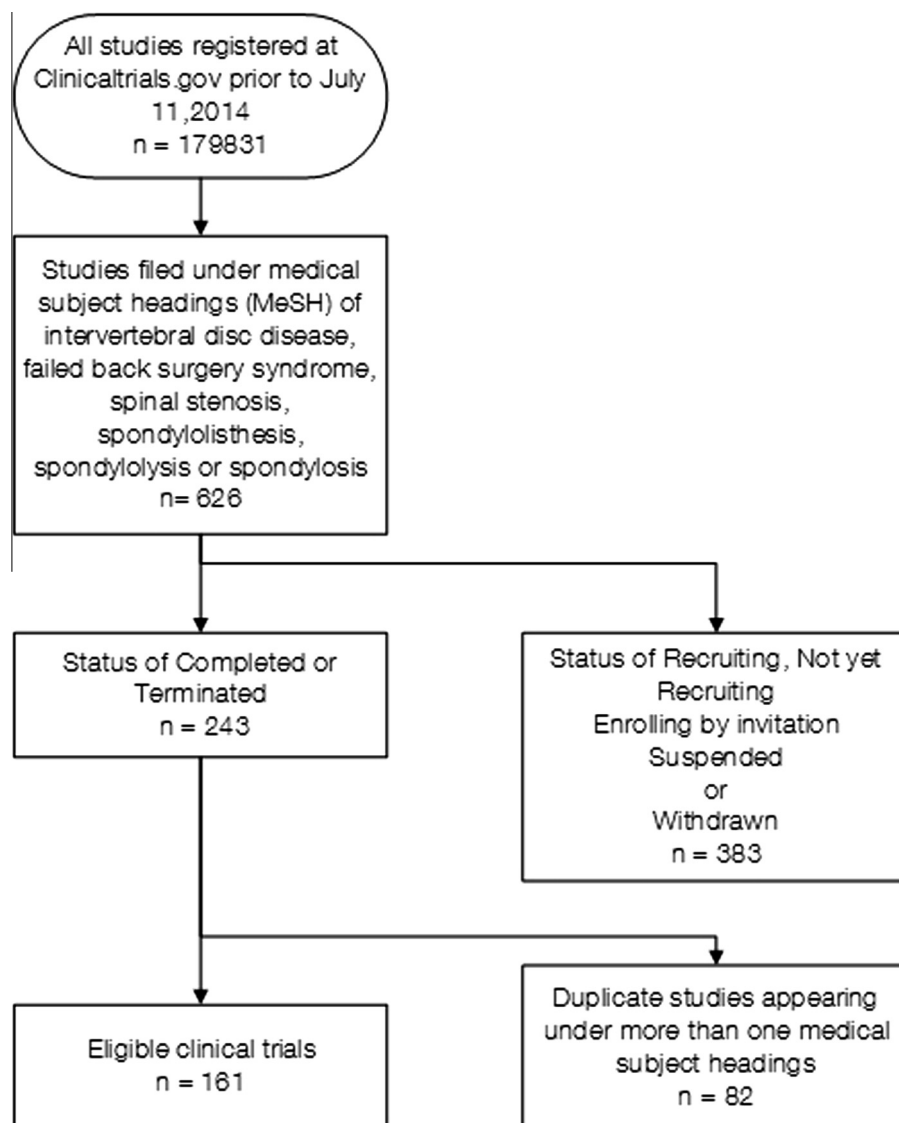
In July 2014 all clinical trials registered at clinicaltrials.gov and categorized under the medical subject headings (MeSH) of “spinal stenosis,” “spondylolisthesis,” “spondylolysis,” “spondylosis,” “failed back surgery syndrome,” and “intervertebral disc degeneration,” as representing degenerative spinal diseases, were collected following a search. We then further limited this query to studies whose status within the database was “terminated” or “completed.” This former status represents one in which a clinical trial had been initiated, patients had been enrolled, but the trial had been stopped prior to a prospective end point for any reason. The latter status represents a one in which the “last subject, last visit” has occurred as defined by clinicaltrials.gov. Registered trials whose status within the database was unknown, “recruiting,” “not yet recruiting,” “active, not recruiting,” “enrolling by invitation,” “suspended” or “withdrawn” were excluded. These statuses represent trials that are actively ongoing, and from which results would not be expected, or trials which were aborted prior to the enrollment of any patients. Following identification of those trials under these six subject headings and with statuses of “terminated” or “complete,” duplicate studies appearing under multiple subject

headings were excluded. A diagram of the query of the clinicaltrials.gov database appears in [Figure 1](#).

The trials meeting these eligibility criteria then had a number of data points from the clinicaltrials.gov database collected. Their sponsors, phase, number of enrollees, start date, last updated date, completion or termination date, principal investigator (if listed), other MeSH/keywords, national clinical trial identification number and other identification numbers (if listed) were recorded.

We bimodally classified trials initially by sponsorship as listed within the clinicaltrials.gov database. Those trials within the database with any commercial entity listed as sponsor were classified as industry funded while those with only non-commercial entities listed as sponsors were classified as non-industry funded. Following PubMed and Google Scholar searches, as described below, the author disclosures of trials for which manuscripts were available were referenced to assess if those disclosures matched with the trial sponsors listed within clinicaltrials.gov. Subsequently, those trials with author disclosures of commercial support in their publications were also classified as industry funded.

The clinicaltrials.gov database has an optional feature in which results from registered clinical trials may be submitted. Results for each eligible trial were thus sought initially within the



**Fig. 1.** Diagram showing the query process of the clinicaltrials.gov database to identify publication bias in industry funded clinical trials of degenerative diseases of the spine.

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