

ANALYSIS OF "HERBAL/ALTERNATIVE MEDICINE" TRIALS SUBMITTED TO CLINICALTRIALS.GOV DATABASE

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BACKGROUND: An important portion of patients with cancer uses remedies under the name of "herbal therapy", "alternative medicine" or "complementary treatment". Most patients confidently use these products because they are labeled as "natural". However, no safety and efficacy data is available for many of these products. In this analysis, we aimed to determine the quantity and quality of herbal/alternative medicine research among recent cancer studies. We analyzed herbal/alternative medicine studies which have been submitted to clinicaltrials.gov database.

PATIENTS AND METHOD : ClinicalTrials.gov is affiliated to National Institution of Health and is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. "Cancer AND (herbal OR complementary OR alternative) " key words have been browsed in this database (access date 17 April 2015). From the results, 163 trials, which have been conducted in patients with the diagnosis of cancer were identified and included in this analysis.

RESULTS: Characteristics of the trials are shown in Table 1. Seventy-two trials have been completed, 37 trials are still recruiting patients and 10 trials have been withdrawn. Most common cancer type was breast cancer. 88% of trials were interventional and 60% of trials were randomized. Rate of new trial submission were similar for 5-year periods after 2000. Majority of the trials were conducted in United States of America (55%) and Public Republic of China (11%). Nine and 4 of 37 trials which are still recruiting were recorded as phase II and phase III, respectively. In one of the phase III trials, acupuncture application for side effects of aromatase inhibitors was investigated. In the remaining 3 phase III trials, efficacy of melatonin, traditional Chinese medicine applications and a herbal mixture were investigated in lung cancer treatment. When browsing was restricted to "recruiting" and "interventional" studies, ratio of herbal/complementary treatment trials to all chemotherapy trials was 1.8 %.

CONCLUSION: In this analysis, we found that there are only few herbal/complementary treatment trials registered in clinicaltrials.gov web site. Ratio of these trials to all chemotherapy trials that have been registered in same time period was 1.8%. Herbal therapies come into the market without sufficient efficacy/safety data, and without passing through the necessary clinical research phases which every pharmaceutical drug has to go through before licensing. In 2014, 51 billion dollars were spent for cancer drug research/development studies¹. The time spent for developing a successful pharmaceutical product is more than 10 years. Unlike pharmaceutical products, herbal/complementary therapies are not subjected to strict legal regulations. As a result, these remedies are marketed without the need of "long-term" and "expensive" clinical research. It is crucial that every discipline which is employed in cancer treatment has to conduct well designed clinical trials on herbal/alternative treatment modalities and has to counsel patients on not using such products without sufficient evidence of efficacy and safety.

REFERENCE

1- Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA annual membership survey. Washington, DC: PhRMA; 2015.

Table 1. Characteristics of trials

	FOR ALL TRIALS n (%)	For only recruiting trials n (%)
Total trial number	163 (100)	37 (100)
Recruiting	37	
Terminated	8	
Completed	72	
Withdrawn	10	
Active, not recruiting	21	
Other	15	
Cancer type		
Breast	50	11
Lung	12	3
Colorectal	15	4
Other	46	9
General (not specified, under the title “cancer” or “neoplasm”)	40	10
Phase		
1	12	0
1+2	15	3
2	45	9
2+3	3	1
3	13	4
4	4	0
Not stated	69	20
Age group		
Adult	143	31
Child	2	1
Adult+child	18	5
Sponsor		
NIH	63	9
Industry	10	2
Other	90	
Type of trial		
Observational	18	5
Interventional	144	32
Early approach	1	
Design of trial		
Randomized	97	16
Other	66	21
Time of trial start		
<2000	5	1
2000-2005	53	2
2006-2010	46	13
>2011	49	20
Not stated	10	1
Intervention		
Drug/biologic/diet supplement	54-5-14	14-1-4
Behavioral	31	9

Device/Procedure	25	4
Other	24	1
Not stated	10	4