



## ORIGINAL ARTICLE

### Drug cost avoidance in prostate cancer clinical trials<sup>☆</sup>



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#### KEYWORDS

Economic benefits;  
Cost avoidance;  
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#### Abstract

**Objectives:** Economic impact of prostate cancer is increasing in relation to its increased incidence and increased patient survival. Clinical trials are essential to evaluate the efficacy and safety of new treatments but may also result in economic benefits by avoiding the cost of the drug. Our objective is to determine the avoided cost in investigational drugs in clinical trials of prostate cancer conducted in a period of 18 years in a tertiary center.

**Material and methods:** We carried out an observational of prevalence study with retrospective collected data of clinical trials involving currently marketed drugs and cost avoidance during the study period (1996–2013) was calculated.

**Results:** We include in this review five clinical trials on prostate cancer that met selection criteria of 18 performed. All of them were phase III, multicenter, international and with current marketed drugs. 136 patients were included. Total cost avoidance of €696,002 and an average cost avoidance by clinical trial of €139,200 were obtained. Average cost avoidance per patient was €5118.

**Conclusion:** Cost avoidance in investigational drugs is a tangible benefit of clinical trials, whose realization is a source of economic benefits for the hospital, not only by directly generated by each trial. Clinical trials are an exceptional framework for progress in clinical research and real savings for the health system.

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**PALABRAS CLAVE**

Beneficio económico;  
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Medicamento en  
investigación;  
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**Coste evitado en medicamentos de ensayos clínicos en cáncer de próstata****Resumen**

**Objetivos:** El impacto económico del cáncer de próstata es cada vez mayor, teniendo en cuenta el incremento de su incidencia y la mayor supervivencia de los pacientes. Los ensayos clínicos son esenciales para la evaluación de la eficacia y seguridad de los nuevos tratamientos, pero también pueden suponer un beneficio económico al evitar el coste derivado del fármaco. Nuestro objetivo es determinar el coste evitado en medicamentos en investigación en los ensayos clínicos en cáncer de próstata realizados en un período de 18 años en un centro de tercer nivel. **Material y métodos:** Se realizó un estudio observacional de prevalencia, con recogida de datos retrospectiva de los ensayos clínicos realizados en los que se utilizaron medicamentos comercializados actualmente. Se calculó el coste evitado durante el periodo de estudio (1996–2013). **Resultados:** De los 18 ensayos clínicos realizados sobre cáncer de próstata se incluyeron en el presente trabajo 5 que cumplieron criterios de selección, todos ellos fase III, multicéntricos e internacionales y con fármacos actualmente comercializados. Incluyeron 136 pacientes. Se obtuvo un coste evitado global de 696.002 €, un coste medio evitado por ensayo clínico de 139.200 € y un coste medio evitado por paciente de 5.118 €.

**Conclusiones:** El coste evitado en medicamentos en investigación es un beneficio tangible de los ensayos clínicos, cuya realización supone una fuente de ingresos para el hospital, no solo por los generados directamente por cada ensayo. Los ensayos clínicos suponen un contexto excepcional para el avance en investigación clínica, así como un ahorro real para nuestro sistema sanitario. © 2015 AEU. Publicado por Elsevier España, S.L.U. Todos los derechos reservados.

**Introduction**

The impact of cancer care is a significant economic burden, both in its prevention and management.<sup>1</sup> Prostate cancer is one of the most frequent oncological diseases, worldwide being the second most common malignancy in men, accounting for 12% of newly diagnosed cancers in Europe<sup>2</sup> and estimating an incidence in 2012 of 27,853 cases diagnosed in Spain.<sup>3</sup>

Clinical trials (CT) are essential to evaluate the efficacy and safety of new treatments. Participation in these offers patients the opportunity to access therapies not yet available, as well as contributing to scientific progress. While the intangible benefits are obvious for patients, researchers and managers, the tangible benefits of carrying out CTs are not as well documented.<sup>4</sup> An economic benefit of CTs, poorly quantified, is the cost avoided in drugs because of their free contribution by promoters.

The avoided cost is defined as an expense that would have had to be paid if the patient had not taken part in a CT with free supply of drugs.<sup>5–7</sup> In the current context of cost containment, it seems advisable to know the cost avoided in research drugs, which increasingly affect a larger number of patients. In recent years there has been an increase in the number of approved CTs,<sup>8</sup> and according to data of the Spanish Agency for Medications and Healthcare Products, in the period 2009–2013 the situation in relation to the authorization of CT in Spain has shown a fairly stable tendency.<sup>9</sup>

In our study, we consider the avoided cost in drugs such as the cost that these drugs would mean for the health system if the patients had not been included in a CT, regardless of their prescription conditions and considering the costs applicable in each case.

Our goal is to determine the avoided cost in medicines in CT research in prostate cancer conducted by the department of urology of our hospital, over a period of 18 years, from the perspective of the national health system.

**Material and methods**

An observational prevalence study was conducted, with retrospective collection of data of CTs in prostate cancer performed by the urology department at a tertiary university hospital complex (1419 beds) in a health area of 557,357 inhabitants, during the period 1996–2013.

The selection criteria considered were the following:

**Inclusion criteria:** CTs initiated during the period of study with investigational drugs currently on the market that allow for a direct economic valuation.

**Exclusion criteria:** CTs with drugs where it is not possible to carry out direct economic valuation and CT without included patients.

The data sources used were the files of each CT, the software application of CT management of the pharmacy service, the database BotPlus<sup>®</sup> to determine the recommended retail price of each drug (RRP), and the software application of management of the pharmacy service to determine the purchase price of medicines for hospital use and hospital diagnosis with hospital dispensing (laboratory sale price: LSP).

**Recorded data:** CT title, protocol code, phase, promoter, masking, field, investigational drugs, scheme and duration of the treatment, starting date and ending date of the CT, prescription conditions, and marketing year of the investigational drug.

To calculate the avoided cost, the following aspects were analyzed:

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