Science For A Better Life

Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

Title	A Drug Utilization Study of Xofigo Use in Sweden
Keywords	Xofigo, off-label use, prostate cancer
Rationale and background	Prostate cancer is the second most common cancer and the sixth leading cause of cancer mortality among men worldwide. A large number of men have disseminated disease at diagnosis or have a relapse after treatment with curative intent. Bone metastases and their clinical sequelae are among the most frequent and debilitating complications in patients with castration resistant prostate cancer (CRPC). Xofigo, an alpha- emitter is a calcium mimetic that self-targets areas of increased bone turnover in bone metastases. It emits high-energy alpha particles of short range that produce a highly localized cytotoxic effect in the target areas. Xofigo was approved in the European Union on November 13, 2013 for the treatment of adults with CRPC, symptomatic bone metastases and no known visceral metastases. Xofigo is contraindicated in women who are or may become pregnant. Xofigo has not been tested on children. The purpose of this study was to evaluate use of Xofigo including potential off-label use in a post marketing setting.
Research question and objectives	The objective of this study was to evaluate the extent of potential off-label use of Xofigo, in Sweden. The study included patients for whom a medical decision had previously been made to treat with Xofigo in Sweden. The study objectives were: • To estimate the use of Xofigo in men with mCRPC • To estimate the use of Xofigo in women. • To estimate the use of Xofigo in children. • To estimate the use of Xofigo in patients with bone metastasis but having a diagnosis of other cancer than castration resistant prostate cancer. • To estimate the use of Xofigo in dosage level (kBq/kg) and number of doses outside recommendations.
Study Design	This was a single-arm descriptive observational drug utilization study based on secondary data collection of patients treated with Xofigo in Sweden.
Setting	The study population were patients receiving treatment with Xofigo at nuclear medicine centers in Sweden during a two-year period.
Subjects and Study Size, including dropouts	Patients receiving Xofigo with data recorded at nuclear medicine centers in Sweden between 01 July 2014 and 30 June 2016 were included in the study. Patients participating in clinical trials were excluded. Data from 12 out of 17 centers treating patients in Sweden during the time period was obtained.

Variables and Data sources	Study variables included patients' age, gender, cancer diagnosis / treatment indication, dosage level (kBq/kg) and number of doses.
Results	A total of 310 patients were included in the study. Of these, 306 (98,7%) had mCRPC. Four (1,29%) patients were treated for an indication other than mCRPC, 2 with breast cancer, 1 with lung cancer, and 1 with osteosarcoma. All these patients had bone metastasis. One patient in the mCRPC group had both skeletal and visceral metastasis at time of treatment. Two (0,64%) women were treated with Xofigo, both with breast cancer. No children (under 18 years) were treated with Xofigo. No patient was treated with more than 6 doses. 1.7 % of evaluable doses were given either with less than 90% of planned dose or more than 110% of planned dose.
Discussion	In this study of contemporary Xofigo use in Sweden, a low rate of off-label use and no use of children (<18 yrs) were observed
Marketing Authorisation Holder(s)	Bayer AG, Germany
Names and affiliations of principal investigators	[redacted]