

# Increased cancer risk following the use of radioactive Radium-224 in the therapy

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Ankylosing Spondylitis (Bechterew's Disease) is a painful chronic inflammatory rheumatic disease, associated with stiffening of the vertebral column. Between 100,000 and 150,000 cases have already been diagnosed in Germany, but milder forms of the disease may remain undiagnosed.

The research team, led by Dr. Roland R. Wick, with Dr. Elke A. Nekolla, Prof. Dr. Albrecht M. Kellerer and the late Prof. Dr. Wolfgang Gössner have conducted a long-term follow-up study of 1,471 ankylosing spondylitis patients, whose disease symptoms were treated with repeated intravenous injections of <sup>224</sup>Radium. A control cohort of 1,324 ankylosing spondylitis patients treated without the use of radioactive compounds and/or X-rays were also studied.

In the current publication an elevated rate of leukaemias was seen, a malignant disease of the haematopoietic system: In all, 19 observed cases of leukaemia were documented compared with 6.8 cases that would be expected in an age- and gender-matched cohort of a normal population. In particular, the incidence of acute myeloid leukaemia was significantly increased with 7.0 cases compared with 1.8 cases expected in a "normal" population.

Furthermore, four additional cases of preleukaemic diseases of the bone marrow were present in the exposed group and no cases in the control group. The frequency of leukaemia was not increased significantly in the control group compared with the expected value for a normal

population.

"It is rather unlikely that impurities present in the radium preparations used before 1950 are responsible for the elevated appearance of myeloproliferative diseases in the exposed group observed here," commented Dr. Roland R. Wick. "In addition, the increased incidence of leukaemia is in line with experimental observations involving the treatment of animals with similar alpha emitting radioisotopes."

The results of these studies by the Helmholtz Zentrum München have contributed decisively to <sup>224</sup>Radium preparations being declared obsolete and have resulted in the revocation of the licensing of SpondylAT ® by the Federal Institute for Drugs and Medical Devices (BfArM) and the decision by the licence holders to discontinue development of the treatment. In earlier legal proceedings the Cologne Administrative Court, in its decision of October 26th, 2006, came to the conclusion that the "increase of myeloid leukaemia [...] could be explained causally with the deposition of radium as a calcium-like element into the bone", because, due to its short half-life of only 3.66 days, the radiation released from <sup>224</sup>Radium has its effect mainly at the bone surface in the proximity of the blood-forming bone marrow cells.

Although previous studies have shown that radium treatment has an analgesic effect the risks of <sup>224</sup>Radium treatment exceed its benefit, particularly, since there are many other therapeutic options available. Accordingly, the Committee for Quality Assurance of the German Society for Rheumatology no longer include this therapy in its recommendations.

Source: Helmholtz Zentrum München - German Research Center for Environmental Health

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