公募助成「腎不全病態研究助成」研究サマリー

研　究 名　称	医薬品添加剤に含まれるマグネシウムおよびリンが透析患者の血中値に対する影響
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Phosphate binders derived from natural ores contain many elements besides their active ingredient metals

Background:
Most patients undergoing dialysis are required to take many phosphate binder pills to control hyperphosphatemia. Phosphate binders are classified into 2 types: metal (Ca, La, or Fe)-based binders and chemically synthesized polymers. The raw materials of metal-based phosphate binders are natural ores; thus, such binders may contain several other metallic elements.

Method:
We measured the elemental contents in 6 metal-based phosphate binders using an inductively coupled plasma mass - spectrometry (ICP-MS) method.

Result and Discussion:
Despite being in small amounts, ore-derived phosphate binders contained various elements besides their active ingredient metals: Na, Mg, P, Mn, Fe, Sr, Y, Ba, Pb, La, and Nd in 3 Ca-based products; Mg, P, Se, Ce, and Gd in a La-based product; and Na, Mg, Al, P, Ca, Ti, Cr, Mn, Co, Ni, Ge, Ba, and La in 2 Fe-based products.
These elements are considered to be originated from pharmaceutical bulk and from pharmaceutical additives. It is unlikely that some of these elements are immediately harmful to patients. However, it should be emphasized that patients undergoing dialysis do not have a urinary excretion route and are administered many phosphate binder pills every day over a long period of time.

Conclusion:
In the future, pharmaceutical companies may have to disclose standard amounts and/or analytical values regarding the type and quantity of metallic elements in the final formulation or pharmaceutical bulk derived from natural ores.