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A first: FDA OKs antivenom for bark-scorpion

Drug was developed in Mexico, clinically tested through UA

A Mexican-made antivenom that cures children of severe nerve poisoning and was tested in clinical trials through the University of Arizona was approved Wednesday by the U.S. Food and Drug Administration.

The antivenom Anascorp is an antidote to the sting from the small, slender bark scorpion, which is the most common house visitor of all Arizona scorpions. It's also the most dangerous. Small children are at highest risk of severe reactions.

"This is an historic event," said Dr. Leslie Boyer, the lead investigator in the UA clinical trials. "This is the first-ever drug approved for this use by the FDA; the first-ever drug that we are aware of being developed fully in Latin America and subsequently approved by the FDA; the first-ever scorpion antivenom proved effective under controlled clinical trials; and the first-ever antivenom with so few allergic reactions."

The FDA approval is the culmination of a nearly 12-year collaboration of academic and clinical researchers with partners in business and industry from both sides of the border, UA researchers say.

About 200 people - almost all children - require treatment for bark-scorpion stings every year in Arizona. Without antivenom, children stung by scorpions typically require heavy sedation, intensive supportive care and often a ventilator, too. Arizona has the highest concentration of dangerous bark scorpions in the United States.

"This antivenom basically takes symptoms away in a very short time. What was a life-threatening disease that would put kids in the pediatric ICU has become, for most of them, an outpatient disease," said Dr. Andreas Theodorou, a UA professor of pediatrics, chief medical officer of University Medical Center and a member of the research team.

Boyer's research team previously conducted a Tucson study of 15 children who ended up in pediatric intensive care in 2004 and 2005 after a scorpion sting. The FDA's Office of Orphan Products Development paid for the research and the study was published in the New England Journal of Medicine.

All the children were experiencing classic symptoms of poisoning caused by the bark scorpion - abnormal eye movements, uncontrollable thrashing of limbs and respiratory distress.

Eight of the children were treated with Anascorp and their symptoms were resolved in less than four hours, usually in less than two. The seven children who received a placebo continued to experience nerve poisoning for four hours or more and required large doses of sedative medication and extended hospitalization.



The bark scorpion is considered the most venomous type of scorpion in Southern Arizona.
A. E. Araiza / Arizona Daily Star 1999

A second study conducted primarily at the San Carlos Hospital on Arizona's San Carlos Apache Indian Reservation confirmed the first study's findings, UA officials say.

The Mexico City-based pharmaceutical company Instituto Bioclon, which makes the antivenom, and its U.S. partner Rare Disease Therapeutics Inc. supplied it to qualifying hospitals.

The UA expanded its research with funds from the state of Arizona and the Arizona Biomedical Research Commission.

"We have been working together to test the Mexican antivenom under United States rules for close to 12 years, learning a lot from the process and learning from each other," Dr. Alejandro Alagón, an antivenom researcher and adviser to Instituto Bioclon, said in a prepared statement.

"This collaboration has really helped us produce a better product," he continued. "For this project we needed to combine laboratory science, clinical science and a good manufacturer, and we needed to design a good clinical trial."

Until the late 1940s, bark-scorpion stings caused more deaths in Arizona than rattlesnake bites. Around that time, Arizona researchers developed a scorpion antivenom using antibodies developed in goat serum.

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But after supplies of that drug ran out several years ago, no company would agree to make it because it failed to meet modern FDA standards, and caused significant side effects. Anascorp is made with horse serum and doctors say it has caused no serious side effects.

UA officials say the research has attracted attention from numerous countries with venomous creatures that pose problems. Among these is Morocco, where Bioclon, assisted by Boyer and Alagón, plans to begin clinical trials on a similar antivenom to treat stings inflicted by North Africa's deadly scorpions.

The World Health Organization in 2007 called management of scorpion stings, snakebites and potentially rabid mammal bites a global public-health emergency.

Among other things, the WHO has called for action by manufacturers and regulatory bodies to ensure safe and effective antivenoms are available, particularly in developing countries.

SCORPION STINGS

Small children are at highest risk of severe reactions. They can show jerky body and wild eye movements. The majority of stings occurring in older children and adults may be managed at home with basic first-aid measures and follow-up.

First aid should include cleaning the site with soap and water; cool compress; elevating the affected limb to approximately heart level; and taking aspirin or Tylenol as needed for minor discomfort.

Call the Arizona Poison and Drug Information Center at 1-800-222-1222 if a child under 5 has been stung or if an older patient is experiencing more than minor discomfort. Stings occurring in children or any patient experiencing severe symptoms should be seen at a medical facility immediately.

Scorpions are relatively inactive during daylight hours. The majority of stings reported to the poison center occur at night during the warm summer months.

SOURCE: Arizona Poison and Drug Information Center

MORE INFORMATION

The VIPER Institute at the University of Arizona studies applied phylogenetics of venom, combining phylogenetic and drug-development resources across international boundaries, resulting in improved, more cost-effective medical care, it says. More information is at viper.arizona.edu

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