

Vaccine against epidemic gastroenteritis being tested

December 9 2011, by Lin Edwards

(Medical Xpress) -- A new vaccine is being tested in the US that may protect against the norovirus, which causes "stomach flu" or acute viral gastroenteritis, that can occur in confined living settings such as cruise ships, nursing homes, hospitals, schools, and military establishments.

Norovirus illness symptoms include acute onset diarrhea, nausea, vomiting, and abdominal cramps, and the disease can range from being a mere nuisance to extremely severe or fatal, especially in immune-compromised individuals and in people in developing countries. In the US alone <u>norovirus</u> illnesses are responsible for over one million hospitalizations each year.

The team of researchers, led by Dr Robert Atmar of the Baylor College of Medicine in Houston, Texas, have demonstrated for the first time that a vaccine can be effective in preventing illnesses caused by the norovirus. Only one vaccine for gastrointestinal disease currently exists, and this protects against the rotavirus, which causes severe diarrhea in babies and young children.

The norovirus vaccine is not expected to be available for at least five years, and possibly as long as a decade. The vaccine currently being tested contains viruslike particle (VLP) antigens, and is in the form of a dry powder that is inhaled. VLPs mimic the live <u>virus</u> since they are basically the shell of protein that surrounds the virus nucleic acid material, but they do not cause infection themselves. Later research will try other means of delivering the vaccine, and it will be tested on other



strains of norovirus.

The vaccine was tested at four medical centers on 90 volunteers aged 18-50, 77 of whom completed the per-protocol analysis. The volunteers all had either <u>blood group</u> O or A (since B and AB confer some protection against the virus) and were randomly assigned to one of two groups, one given two doses of the vaccine, and the other given two doses of a placebo. Three weeks after the second dose, they were exposed to the Norwalk norovirus strain and then monitored and tested for antibodies indicating a viral infection.

The results were that 82% of those receiving the placebo became infected with the virus and 69% developed gastroenteritis symptoms, while 61% of those who received the virus became infected, only 37% developed symptoms, and in these people the symptoms were less severe. Dr Atmar said the 18% who had the placebo but did not become infected had probably developed immunity through previous exposure to the virus. Side effects of the dry powder spray (vaccine and placebo) included nasal stuffiness, runny nose and sneezing.

Dr Atmar said norovirus strains cannot be tested using animal models because it does not infect them. It is also impossible to grow in a culture, which makes testing difficult. A protein cultured from the virus was found in the 1990s to self-assemble into the VLPs that have now been used to make the vaccine.

Norovirus is highly infectious and can be easily spread via contaminated water and food. At present the only treatment is to replace fluids to avoid dehydration. The best way of avoiding infection is thorough handwashing and washing fruit and vegetables.

The paper was published in the *New England Journal of Medicine* and the research was funded by the <u>vaccine</u> manufacturer, LigoCyte



Pharmaceuticals, and by a grant from the National Institutes of Health.

More information: Norovirus Vaccine against Experimental Human Norwalk Virus Illness, *N Engl J Med* 2011; 365:2178-2187. December 8, 2011. www.nejm.org/doi/full/10.1056/NEJMoa1101245

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