

UBC-Providence Health research to examine new treatments for heroin addiction

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A clinical trial to test better treatment options for chronic heroin addiction is expected to begin in Vancouver at the end of this year. Led by researchers from Providence Health Care and the University of British Columbia, it's the only clinical trial of its kind in North America.

The Study to Assess Longer-term Opioid Medication Effectiveness (SALOME) is a carefully controlled three-year clinical trial that will test whether hydromorphone (Dilaudid), a licensed [pain medication](#), is as effective as diacetylmorphine, the active ingredient of heroin, at engaging the most vulnerable long-term street heroin users, so they will enroll in treatment programs and end their use of [illicit drugs](#).

The intent of the SALOME project is to determine whether some participants become healthier and reduce their [illicit drug use](#) or are able to switch to other forms of treatment. SALOME also intends to test if, after stabilizing patients on injectable medications, they can transition to oral formulations without losing effectiveness.

This study builds on the North American Opiate Medication Initiative (NAOMI), which was North America's first-ever clinical trial of prescribed heroin that took place from 2005 to 2008. NAOMI, which also was led by researchers from Providence [Health Care](#) and UBC, was a [randomized trial](#) aimed at testing whether medically prescribed heroin (diacetylmorphine) was more effective than methadone therapy for individuals with chronic [heroin addiction](#) who were not benefiting from other [conventional treatments](#).

The results, published in the [New England Journal of Medicine](#), showed that patients treated with the prescribed heroin were more likely to stay in treatment or quit heroin altogether and more likely to reduce their use of illegal drugs and other illegal activities than patients treated with oral methadone.

In the NAOMI study, the researchers also provided a small sample of patients with injectable hydromorphone, (Dilaudid®). An unexpected finding was that injection patients could not accurately discriminate whether they were receiving prescribed heroin or hydromorphone. The researchers also observed similar results and benefits with both these drugs although the small number of participants receiving hydromorphone did not permit any definite and scientifically valid conclusions to be drawn as to the efficacy of hydromorphone as a viable treatment option.

Should hydromorphone be proven to be as affective as heroin, the benefits of this form of injectable treatment may be more feasible and achievable without the emotional and regulatory barriers often presented by heroin maintenance.

SALOME, led by Dr. Michael Krausz, the Providence Health Care/UBC B.C. Leadership Chair in Addiction Research and Dr. Eugenia Oviedo-Joekes, Providence Health Care researcher and an assistant professor in UBC's School of Population and Public Health, will enroll 322 individuals with chronic heroin dependency who currently are not sufficiently benefiting from conventional therapies, such as methadone treatment, at one site based in Vancouver, BC.

In the first stage, half of the 322 participants will receive injectable prescribed heroin, and the other half will receive injectable hydromorphone. Stage I will involve six-months of treatment. All volunteers retained in injection treatment at the end of Stage I will be

eligible to enter Stage II.

In Stage II, half of the participants will then continue injection treatment exactly as in Stage I on a blinded basis while the other half will switch to the oral equivalent of the same medication (prescribed heroin or hydromorphone). Stage II will also involve six-months of treatment.

Throughout the treatment period, social workers will be assigned to both groups to assist them with reaching other addiction services and community resources such as counseling, housing and job training services.

Some 60,000 to 90,000 persons are affected by opioid addiction in Canada. This study will enroll the most chronically drug-dependent members of Vancouver's population -- those who are not benefiting from other treatments, such as methadone therapy and abstinence-based programs, and continue injecting street heroin.

"SALOME addresses critical social and ethical concerns dealing with addiction. Opioid-dependent people are in need of treatment options to avoid marginalization from the health care system and this study aims to answer questions that could lead to improvements in the health of persons with chronic addictions and identify new ways of reintegrating this population into society," says Dr. Perry Kendall, B.C.'s Provincial Health Officer. "If the SALOME study shows that hydromorphone can go head-to-head with heroin as an alternative therapy for people who have failed optimally provided methadone, then I think this should be part of the [treatment](#) continuum that's available through licensed physicians."

More information: www.providencehealthcare.org/salome/index.html

Provided by University of British Columbia

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