

**FHS Spring Seminar Abstract**  
**Dr. Martin Schechter**  
**Wednesday February 10, 2010**  
**Blusson Hall 9660**  
**4:30pm – 5:20pm**

**NAOMI:**

**The Trials and Tribulations of Heroin Assisted Therapy**

Opioid dependence, most commonly manifested as heroin addiction, is a chronic, relapsing disease estimated to affect more than one million individuals in North America. Recent studies in Europe have suggested that injectable diacetylmorphine (DAM), the active ingredient in heroin, can be an effective adjunct treatment for such individuals. To investigate this in the North American context, we compared injectable DAM with methadone maintenance therapy (MMT) in individuals refractory to treatment.

NAOMI (North American Opiate Medication Initiative) was a parallel, open-label, phase III randomized controlled trial (n=251) conducted in Vancouver and Montreal between March 2005 and July 2008. Long-term heroin injectors who had not benefited from at least 2 previous treatment attempts were randomized to receive oral MMT (n=111) or injectable diacetylmorphine (n=115). The DAM group could add or switch to methadone if desired. Primary outcomes were: (1) Retention in addiction treatment or drug-free status at 12 months; (2) clinical response at 12 months based on the European version of the Addiction Severity Index (ASI).

Primary outcomes were determined for 95% of participants. Based on intent-to-treat analysis, the rates of retention in addiction treatment in the DAM and MMT groups were 87.8% and 54.1% (RR=1.62; CI 95%=1.35-1.95; p<0.001). The clinical response rates were 67.0% vs. 47.8% respectively (RR= 1.40; 95% CI= 1.11-1.77; p=0.004). The most common serious adverse events with some relation to DAM injections (n=89,924) were overdoses (11) and seizures (7). All were promptly resolved without sequelae or treatment discontinuation.

Injectable diacetylmorphine, administered under medical supervision, offered additional benefits over and above MMT alone for patients with opioid addiction who are refractory to treatment. Conducting a trial of this sort posed a number of scientific, logistic and political challenges that will be discussed.