



## **North American Opiate Medication Initiative (NAOMI)**

### **Questions and Answers**

#### **A. NAOMI Clinical Trial Questions and Answers**

##### **Q1. What is the NAOMI clinical trial?**

A1. The North American Opiate Medication Initiative is a clinical trial that will test whether heroin-assisted therapy benefits people suffering from chronic heroin addiction who have not benefited from other treatments.

##### **Q2. Why is this study being funded?**

A2. NAOMI addresses critical social and ethical concerns dealing with addiction. 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. The researchers hypothesize that heroin maintenance therapy could also help to reduce the use of illicit drugs and drug-related crime.

##### **Q3. When and where is this trial being conducted?**

A3. The trial began enrolling in February 2005 in Vancouver and in June 2005 in Montreal. These cities have the largest heroin-addicted populations in Canada.

##### **Q4. What are the benefits of this project to Canadians and the addicted population?**

A4. Heroin addiction creates tremendous social and health costs. These include crime, diseases such as HIV and Hepatitis C and unemployment. The leaders of the trial believe that prescribed heroin could save Canadians an enormous amount of money and untold suffering. Similar "heroin maintenance" studies conducted in Europe among people with chronic addictions have reported improved health status, decreased use of illicit drugs, significant reductions in criminal activity and increased employment.

##### **Q5. How much does this project cost and who is funding it?**

A5. This trial is being funded by an \$8.1M grant from the Canadian Institutes of Health Research.

**Q6. Why is CIHR investing \$8 million to help persons with heroin addiction when there are Canadians waiting in line-ups for cancer treatments?**

**A6.** CIHR is supporting this research project because it is the major federal agency responsible for funding health research in Canada. Its mandate is to improve the health of Canadians, including vulnerable populations. It is an excellent example of CIHR's investment in solving the health challenges of those in need and it reflects CIHR's goal of broadening our horizon of scientific knowledge and transferring that knowledge to improved health for all Canadians.

CIHR believes this research project will provide valuable information for the treatment of heroin addiction.

NAOMI received a rating of 4.3 out of 5 (the high excellent category) and was ranked fourth out of 72 experiments that were reviewed. It was in the top sixth percentile of the roughly 2000 grants reviewed by CIHR in the same competition.

**Q7. How many persons with heroin addiction are there in Canada? Will this project involve all of them?**

**A7.** There are some 60,000 to 90,000 persons affected by opiate addiction in Canada. This study will enrol the most chronically addicted members of this population in Vancouver and Montreal—those who have not benefited from other treatments, such as methadone therapy and abstinence programs.

**Q8. How much does addiction cost to Canadian society?**

**A8.** Addiction costs Canadian taxpayers hundreds of millions of dollars per year. Illicit drug use costs approximately 0.2 percent of the GNP. A recent “cost of illness” analysis estimated over \$45,000 per year in societal costs per person who has an addiction.

**Q9. Could prescribed heroin therapy reduce these costs?**

**A9.** We do not know; but European studies similar to NAOMI reported improved health status, decreased use of illicit drugs, lower criminal activity and increased employment among addicts treated with heroin. These same studies showed that, overall, prescribed heroin treatment saved much more money than it costs.

**Q10. How will the NAOMI trial ensure that only chronic users participate?**

**A10** Stringent controls have been placed on the screening of participants to ensure that only those who fall within the “chronic” category are selected. The NAOMI study has defined “chronic” as persons with a history of at least five years of documented drug addiction. As well, participants must have been using heroin frequently for at least one year immediately prior to entry into the study.

**Q11. Where will the heroin come from and where will it be kept in a safe location throughout the study?**

A11. It is pharmaceutical-grade heroin manufactured by a pharmaceutical company in Europe. It will be purchased and imported with permission of the Government of Canada. It will be kept in a safe location.

**Q12. Is it legal to provide heroin to persons with an addiction?**

A12. There is a legal mechanism in Canada for making heroin available for federally approved scientific studies.

**Q13. What safety measures are in place to ensure the heroin is not stolen?**

A13. There are clear safety procedures incorporated into the study to ensure protection of staff, participants and the general public. The heroin will be dispensed to subjects in a pre-filled syringe that must be used under the observation of trained health care professionals in the high-security medical clinics developed for the trial. Strict security provisions will prevent the theft of the drug or removal of any of the drug from the medical clinics.

**Q14. How is the trial addressing the concerns of the Canadian public about the study?**

A14. In the last two years Advisory Boards have been established in all three cities participating in the trial. These boards meet regularly and include representatives from provincial medical colleges, government, law enforcement, community groups, addiction medicine, and the opiate-dependent population.

NAOMI has also conducted extensive community consultations in the choice of its Vancouver clinical site, and invited representatives of the business and residential neighbours of the Vancouver site to participate in its Neighbourhood Advisory Committee.

**Q15. Does NAOMI aim to promote legalization of heroin?**

A15. The NAOMI clinical trial does not promote legalization of heroin. The trial seeks rigorous scientific evidence as to the usefulness of medically prescribed heroin in the treatment of a limited number of people with chronic addictions for whom there are currently no effective treatments.

**Q16. By giving heroin to people, won't you create more people who will have a heroin addiction?**

A16. The participants in the study already have had an addiction to heroin for many years and have not benefited from other forms of treatment such as methadone therapy and abstinence programs. The study is intended to find alternative treatment methods that might benefit people who have serious and chronic heroin addiction.

**Q17. How can public funds be used for the purchase of heroin to be given away to people who have a heroin addiction?**

A17. Health Canada has recognized the high social and health costs associated with untreated opiate addiction. The government has endorsed, in principle, research that will help expand the evidence base and the range of available treatment, prevention and harm reduction models.

**Q18. Will people be paid for their involvement in this study? Isn't there something ethically wrong with that?**

A18. Participants will receive an average of \$25 for the time taken to fill in lengthy questionnaires (on six occasions). This small stipend will help to ensure that they remain involved with the study even if they leave the treatment program. This, in turn, will generate more reliable study results. The researchers will be following standard research protocols; compensation amounts have been reviewed by the ethics committees and are in keeping with accepted standards. All research protocols have been reviewed and approved by the three participating research institutions' Research Ethics Boards. Only approved studies are able to move forward.

**Q19. Wouldn't it be better to spend money on preventing people from using heroin in the first place?**

A19. The federal government is funding a range of studies on the prevention of addiction. For example, some of this funding has helped the Centre for Addiction and Mental Health at the University of Toronto and community groups to develop innovative prevention and educational programs, in particular for youth. The participants in the NAOMI clinical trial will, however, be people who have already developed an addiction to heroin and haven't benefited from other forms of treatment.

**Q20. Is the intent for people who receive injection therapy and benefit from it to remain on government supplied heroin for the rest of their lives?**

A20. No. After 12 months in the study, those participants requiring ongoing treatment will be referred to methadone maintenance treatment or another treatment of their choice. Participants will receive injectable medications for no more than 15 months. At each site the study will last no more than two years. The intent of the NAOMI 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.

Studies and programs in Europe suggest that providing people with prescription heroin in a controlled and supervised manner removes the need for them to commit crimes to obtain their drugs. It also introduces participants to an environment where they can get vital support: counselling, the help of social workers and housing officers, employment training and so on. This has allowed many addicted Europeans to live more productive lives and lessen the social and health costs associated with addiction.

**Q21. How will the NAOMI project be conducted?**

A21. The project will be conducted in five phases: Recruitment, Screening, Study Period, Transition Period and Research follow-up.

**Phase 1: Recruitment**

Potential volunteer participants will be recruited in Toronto, Vancouver and Montreal from emergency rooms, service agencies, volunteer lists, needle exchange programs and other sources.

**Phase 2: Screening**

Participants will undergo a screening process to determine if they match the research team's definition of suffering a "chronic" heroin addiction. Their past treatment and addiction level will be documented and they will be required to give informed consent for their participation. This phase is expected to take three weeks.

**Phase 3: Study Period**

At each clinical site, participants will be randomized into one of two groups (70-88 in each group at each site)—a heroin injection group and a methadone therapy group. Members of the heroin group will attend their city's NAOMI treatment clinic, where they will receive an injection of pharmaceutical-grade heroin from a sterile syringe up to three times a day. They will then be observed for 30 minutes until attending medical personnel determine that it is safe for them to leave. Members of the methadone group will attend the clinic once a day for an oral dose of methadone. The administration of prescriptions will be overseen for both groups by addiction medicine specialists.

During this time, the research team will also see each participant regularly at a separate research clinic. Volunteers will fill in questionnaires about their status (Addiction Severity Index, use of illicit drugs during the study period, criminal activity, health status), to provide data for a more accurate picture of the daily lives of people with addiction.

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

At any time, participants may choose to advance to transition to drug-free programs, or to detox programs. Participants remain in the study treatment period for 12 months.

**Phase 4: Transition Period**

In this three-month phase, participants are transitioned to other programs, such as methadone therapy, drug-free programs, or detox programs.

**Phase 5: Research Follow-Up**

To avoid biases in the study, participants will be monitored by the research team even if they choose to leave treatment. The research team will track

them for their outcomes, independent of the treatment program, throughout their treatment and for one year after the transition period.

**Q22. Won't the NAOMI study add to public nuisance problems in the cities where it is conducted?**

A22. Experience from other countries indicates that this will not be a major concern. For example, in Switzerland the heroin program was supported by majorities as high as over 70 per cent in three national referenda.

**Q23. How is this project different from a supervised injection site?**

A23. NAOMI is a rigorously controlled, scientific study that will run for 21 months. Physicians who specialize in addictions management will supervise participants and record data. Participants will receive treatment (prescribed heroin) as well as social supports, so they will not need to engage in the illicit drug trade to feed their addiction.

**Q24. Who is the NAOMI research team?**

A24. The study will be headed by lead investigator Dr. Martin T. Schechter of the University of British Columbia. The other principal investigators include Dr. David C. Marsh, Dr. Aslam H. Anis and Dr. Michael O'Shaughnessey of UBC; Dr. Benedikt Fischer, Dr. Jurgen T. Rehm and Dr. Chris Cavacuiti of the Centre for Addiction and Mental Health at the University of Toronto; and Dr. Suzanne Brissette, Dr. Serge Brochu and Dr. Pierre Lauzon of Université de Montréal.

**Q25. Who else is involved in this project?**

A25. Vancouver's University of British Columbia; Toronto's Centre for Addiction and Mental Health and the University of Toronto; and Montreal's St. Luc Hospital and Université de Montréal.

**Q26. What is the current situation regarding drug addiction research in Canada?**

A26. Given the magnitude of the addiction problem, the NAOMI research team believes that there is too little addiction research being funded and conducted on national and international scales. In Canada, we must build up the research capacity that we have lost to other countries over the past decade. Providing strong career opportunities for Canadian scientists and research teams is a primary goal of CIHR.

Investigators in Switzerland who treated 1,100 addicted people with medically-prescribed heroin reported encouraging results; however, their study was different from the NAOMI clinical trial in that it did not include a control group. The Dutch have now completed a randomized trial, but it has a different design from NAOMI in that it deals with inhaled or smoked (rather than injected) heroin.

## **B About CIHR research projects**

### **Q27. Can you explain how CIHR research projects are selected?**

A27. An efficient use of public funds demands that only significant research be supported. Therefore, all funding applications are reviewed independently by the best scientists in the field. More than 400 individuals volunteer their time, talents and energies to the 40 different peer review committees charged with reviewing applications. Their goal is to select those research proposals that demonstrate the greatest scientific merit and potential contribution to knowledge. The criteria used to evaluate proposals include excellence, breadth of vision, research at the leading edge, benefit to the health of Canadians, and partnership at all levels.

CIHR's peer review process is renowned internationally for its rigor and the gold standard of research excellence that it maintains. Peer review committees (Standing Committee on the Oversight of Grants and Awards Competition) submit their recommendations to the Governing Council of CIHR, which makes the final decision. In addition, each scientific study must be approved by the Ethics Committees of all participating hospitals or institutions.

### **Q28. What do research grants pay for?**

A28 Grant funds are used solely for research expenditures, including salaries for research assistants and technicians and the supplies needed for the laboratory. They are not used for overhead expenditures, or to pay a salary or stipend to principal investigators. Research grants are paid up for a specified duration and are subject to periodic review.

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