AUSTRALIA'S FIRST TRIAL OF SUPERVISED INJECTABLE OPIOID TREATMENT (SIOT) WITH HYDROMORPHONE FOR PEOPLE WITH OPIOID USE DISORDER: AN OPEN LABEL TRIAL

Authors:
Rodgers C[1,2], Bell J[3], Ezard N[1,2,4,5], Ritter A[6], Treloar C[7], Roberts D[1], Jauncey M[3], Belackova V[3,8], Dore GJ[9], Goodman-Meza D[1,9], Steele M[1], Dunlop A[2,10,11], Lintzeris N[2,12,13], Shanahan M[5], van den Brink W[14], Strang J[15], Oviedo-Joekes E[16], Siefried KJ [1,2,4,5]

[1] Alcohol and Drug Service, St Vincent's Hospital, Sydney, Australia
[2] New South Wales Drug and Alcohol Clinical Research and Improvement Network (DACRIN), NSW, Australia
[3] Uniting NSW.ACT
[4] National Centre for Clinical Research on Emerging Drugs (NCCRED), University of NSW, Australia
[5] National Drug and Alcohol Research Centre (NDARC), University of NSW, Australia
[6] Drug Policy Modelling Program, University of NSW, Sydney, Australia
[7] Centre for Social Research in Health, University of NSW, Sydney, Australia
[8] Kirketon Road Centre, Sexual Health and Blood Borne Virus Services, South Eastern Local Health District Sydney
[9] Kirby Institute, University of NSW, Sydney, Australia
[10] Drug and Alcohol Services, Hunter New England Local Health District, Newcastle, NSW, Australia
[11] Hunter Medical Research Institute, University of Newcastle, Newcastle, NSW, Australia
[12] Drug and Alcohol Services, South Eastern Sydney Local Health District, Surry Hills, NSW, Australia
[13] Discipline of Addiction Medicine, University of Sydney, NSW, Australia
[14] Amsterdam University Medical Centres, Department of Psychiatry, Amsterdam, The Netherlands
[15] National Addiction Centre, Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK
[16] School of Population and Public Health, University of British Columbia Centre for Health Evaluation & Outcome Sciences, Providence Health Care, Vancouver, BC, Canada

Background:
Supervised Injectable Opioid Treatment (SIOT) is a second line, evidence-based intervention for the treatment of opioid dependence. This trial assessed the feasibility of time-limited SIOT using injectable hydromorphone in an Australian opioid treatment program (OTP).

Methods:
Single-site, single-arm, open-label trial conducted in an OTP within a tertiary public hospital in Sydney, Australia. Eligible adults were recruited to receive up to 24 months of twice-daily, supervised, injectable hydromorphone plus standard opioid agonist treatment (OAT). With cessation of hydromorphone, participants were offered ongoing OAT and followed for a further 3 months.

Measurements:
Retention and participation in treatment were assessed by days of hydromorphone treatment; days of OAT medication; missed days of dosing; and number of participants retained on OAT at three months post last dose of hydromorphone. Data were collected at baseline, 12 months and 3 months following final hydromorphone dose.

Results:
Sixty-nine people expressed interest, 53 were pre-screened, and 22 enrolled with at least one hydromorphone dose. Fifteen participants were retained on OAT at three months following cessation of hydromorphone; 9 participants discontinued hydromorphone treatment before 24 months, and 7 participants were not retained. For 15 participants retained on OAT, median heroin

use in previous 28 days decreased from 26 days at baseline to four days at month 27. Quality of life and mental health outcomes improved, and criminal activities decreased.

There were 379 adverse events in 20 participants, 141 related to hydromorphone, most commonly gastrointestinal (n=67). There were eight Serious Adverse Events (SAEs) in four participants, with two non-fatal SAEs in one participant that included airway management +/- administration of naloxone, which were safely managed in the clinic. One SAE was a death, not temporally related to hydromorphone dosing.

Conclusion:

These findings demonstrated the capacity to develop and implement a SIOT service in an existing OTP setting and deliver a time-limited intervention. Retention levels in the trial support intervention feasibility.

Declaration of interests

John Strang, through his university, has worked with several pharmaceutical companies to identify new or improved treatments, and his employer (King's College London) has received grants, travel costs and/or consultancy payments. None of these are related to the current study which this paper describes.

Nicholas Lintzeris has received funding for independent research from Indivior and Camurus for work unrelated to this project.

Krista Siefried and Nadine Ezard have received funding from the Australian Department of Health and Aged Care and is employed by the University of New South Wales and St Vincent's Hospital, Sydney.

Willem van den Brink, has worked with several pharmaceutical companies to identify new or improved treatments and received speaker fees, travel costs and/or consultancy payments. None of these are related to the current study.