Journal of Substance Abuse Treatment 59 (2015) 52–58

Contents lists available at ScienceDirect

Journal of Substance Abuse Treatment

A Phase 4, Pilot, Open-Label Study of VIVITROL® (Extended-Release Naltrexone XR-NTX) for Prisoners

Michael S. Gordon, D.P.A. [a,b,*], Timothy W. Kinlock, Ph.D. [a,c], Frank J. Vocci, Ph.D. [a], Terrence T. Fitzgerald, M.D. [d], Asli Memisoglu, Sc.D. [e], Bernard Silverman, M.D. [e]

[a] Friends Research Institute, Inc.
[b] Department of Criminal Justice, Stevenson University
[c] School of Criminal Justice, University of Baltimore
[d] Glenwood Life Counseling Center
[e] Alkermes, Inc.

ARTICLE INFO

Article history:
Received 6 April 2015
Received in revised form 7 July 2015
Accepted 13 July 2015

Keywords:
Long-acting naltrexone
Prisoners
Heroin addiction

ABSTRACT

This was a Phase 4, pilot, open-label feasibility study of extended-release injectable naltrexone (XR-NTX) administered to pre-release prisoners having a history of pre-incarceration opioid disorder. We evaluated the relationship between XR-NTX adherence and criminal recidivism (re-arrest and re-incarceration) and opioid and cocaine use. Twenty-seven pre-release male and female prisoners who had opioid disorders during the year prior to index incarceration were recruited and received one XR-NTX injection once each month for 7 months (1 injection pre-release from prison and 6 injections in the community) and of those 27, 10 (37%) were retained in treatment at 7-months post release. Results indicate those completing 6 compared to those completing <6 injections were less likely to test positive for opioids in the community (0% vs. 62.5%, respectively; $p = 0.003$). Although not statistically significant, individuals who did not complete all 6 injections were more likely to be re-arrested compared to those completing all 6 community injections (31.3% vs. 0%, respectively; $p = 0.123$). Contingent upon further study of a randomized controlled trial, XR-NTX may be a feasible option in the prison setting in view of the lack of potential for diversion. Furthermore, these data suggest that completing the entire course of treatment (6 injections) may reduce opioid use and, to a lesser degree, re-arrest and re-incarceration.

© 2015 Elsevier Inc. All rights reserved.

1. Introduction

Disorders involving opioid use are a severe problem among jail and prison inmates. Inmates in the US, Canada, Australia, and many European and Asian nations have disproportionately higher rates of opioid use disorders than their general populations (Dolan, Khoei, Brentari, & Stevens, 2007; Fazel, Bains, & Doll, 2006; Kanato, 2008; Kastelic, Pont, & Stöver, 2008; Kinlock, Gordon, & Schwartz, 2011). In the US, there are over 1.5 million state and federal prisoners (Carson & Golinelli, 2013), of whom an estimated 12%–15% have histories of opioid dependence (Mumola & Karberg, 2006).

Scarce resources are provided for corrections-based substance use treatment in many nations, and many inmates with OUDs remain untreated (Dolan et al., 2007; Kastelic et al., 2008; Kinlock et al., 2011; Taxman, Perdoni, & Harrison, 2007). As a consequence, opioid use either continues or resumes rapidly after release from incarceration (Kinlock et al., 2011; Strang et al., 2006), placing newly released inmates at extremely high risk for death from drug overdose (Binswanger et al., 2007, 2011; Bird & Hutchinson, 2003; Farrell & Marsden, 2008; Krinsky, Lathrop, Brown, & Nolte, 2009; Merrall et al., 2010; Stewart, Henderson, Hobbs, Ridout, & Knuiman, 2004). Opioid use among newly released inmates also has adverse public safety consequences, as it puts individuals at an increased risk for criminal activity (Hough, 2002; Inciardi, 2008; Kinlock, Gordon, & Shabazz, 2015; Kinlock, O'Grady, & Hanlon, 2003) and re-incarceration (Binswanger et al., 2007; Hough, 2002; Kinlock et al., 2015; Metz, Matzenauer, Kammerer, et al., 2010). Individuals with OUDs regularly engage in criminal activity, mainly illicit drug trafficking, often on a daily basis; such trafficking, in turn, typically leads to greater rates of violent crime, while there are others who engage primarily in property offenses (Brownstein, 2013; Latkin et al., 2013).

There is a growing body of evidence supporting the effectiveness of opioid agonist pharmacotherapy in jail and prison settings for both inmates who were using opioids at initiation of maintenance treatment (Dolan, Shearer, MacDonald, et al., 2003; Hedrich et al., 2012; Magura, Rosenblum, Lewis, & Joseph, 1993, Magura et al., 2009; Stover & Michels, 2010; Tomasino et al., 2001) and inmates who had been previously, but not currently, opioid-dependent (Dole et al., 1969; Gordon, Kinlock, & Schwartz, 2008; Kinlock, Gordon, Schwartz, Fitzgerald, & O'Grady, 2009, Kinlock, Gordon, Schwartz, & O'Grady, 2008, Kinlock et al., 2007, 2009). In addition, there is increasing evidence that the use of XR-NTX (an opioid antagonist) may be a feasible and effective

* Corresponding author at: Friends Research Institute, Inc., 1040 Park Avenue, Suite 103, Baltimore, MD, 21201. Tel.: +1 410 837 3977x251.
E-mail address: mgordon@friendsresearch.org (M.S. Gordon).

http://dx.doi.org/10.1016/j.jsat.2015.07.005
0740-5472/© 2015 Elsevier Inc. All rights reserved.

intervention for individuals with OUD who are under criminal justice supervision (Di Paoloa et al., 2014) and warrant further investigation with criminal justice populations (Lee, Friedmann, Boney, et al., 2015; Lee, McDonald, et al., 2015). Nonetheless, many American prison and jail administrators remain reluctant to offer this opioid agonist pharmacotherapy in their facilities, largely due to preference for drug-free interventions (Friedmann et al., 2012; Nunn et al., 2009; Rich et al., 2005; Zaller et al., 2013) and concerns surrounding medication diversion, especially with buprenorphine (Wish et al., 2012). Extended-release injectable naltrexone (XR-NTX; brand name VIVITROL®) has been found to be feasible and promising in reducing opiate use for participants in community corrections (probation and parole) populations in the US (Coviello et al., 2012; Lee, Friedman, McDonald, et al., 2015); jail inmates in the US (Lee, McDonald, et al., 2015) and for Russian heroin-dependent individuals (Krupitsky, Zvartau, & Woody, 2010). Results from Russia are especially noteworthy as this was one of the first studies that established XR-NTX's efficacy for opioid relapse prevention. Furthermore, it is a nation with one of the highest rates of heroin addiction in the world, and methadone and buprenorphine are not available (Krupitsky, Zvartau, & Woody, 2010).

Naltrexone blocks the intoxicating and reinforcing effects of opioids, but has no opioid-like effects. When taken regularly, it reduces opiate-taking behavior (Gastfriend et al., 2005; Krupitsky et al., 2010). XR-NTX is supplied as a microsphere formulation of naltrexone for suspension and is administered by intramuscular (IM) gluteal injection every 4 weeks. In 2010, it was approved by the Food and Drug Administration (FDA) for the prevention of relapse to opioid dependence, following opioid detoxification. Administered as a monthly injection, XR-NTX eliminates the need for adherence to daily oral therapy and continues to demonstrate blockade of opioids for over 30 days, and thus has the potential to improve outcomes for OUDs.

In contrast to individuals at large in the community, who have full opportunity to use drugs, most prisoners in the US with OUD histories do not have full opportunity to use drugs in prison (although drug use occurs, it is typically more occasional rather than regular use) (Gordon et al., 2014; Kinlock et al., 2011). Therefore, and unlike most jail inmates, who have relatively short incarceration stays and do not lose their tolerance to opioids, many of these prisoners lose their tolerance to the respiratory depressant effects of opioids during incarceration. This is important because if untreated, such individuals have increased susceptibility to opioid overdose upon release from prison. Finally, controlled environments offer an excellent opportunity to initiate XR-NTX because individuals who were opioid-dependent prior to imprisonment have a high likelihood of being abstinent in the controlled correctional environment for the required length of time prior to initiating XR-NTX treatment. Thus, increased access to effective treatment interventions that begin during incarceration and continue in the community is needed for inmates with heroin addiction histories (Chandler, Fletcher, & Volkow, 2009; Dolan et al., 2007; Kinlock et al., 2011).

In conclusion, demonstrating the effectiveness of XR-NTX in a prison setting may serve to make at least this medication available to those who wish to take it. It may also be a precursor to greater attitude changes by correctional staff to the use medications to treat opioid addiction, which could lead to the use of agonist medications. Currently, most individuals who are incarcerated in the United States do not have access to any pharmacotherapy for opioid addiction. Thus, making XR-NTX available in some institutions would be an advance. Furthermore, it is likely to improve public health because it affords 30 days of protection from relapse and overdose during the most vulnerable time post-release. For these reasons, we believe that it has potential benefit to some (but not all) incarcerated individuals with opioid dependence.

1.1. The present study

This was a Phase 4, pilot, open-label study of XR-NTX administered to pre-release prisoners presenting with a history of pre-incarceration opioid dependence according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR). XR-NTX was administered according to the approved label. Twenty-seven eligible, consenting pre-release participants were enrolled at 4 Baltimore, MD area prisons (3 for men, 1 for women). Study drug was scheduled to be administered by intramuscular (IM) injection, once monthly (every 28 days), for 7 months. Regular assessments included urine drug tests and routine safety assessments. Participants were to be assessed at 10 time points: at screening (study entry: approximately 1 month prior to release from prison), at baseline (approximately 1 week prior to release), and then monthly for 6 treatment visits, an end of treatment visit, and a safety follow-up visit following their release from prison. This study was approved by Friends Research Institute's Institutional Review Board (IRB) and by the Maryland Department of Public Safety and Correctional Services (DPSCS) Research Committee.

2. Methods

2.1. Eligibility criteria

2.1.1. Inclusion criteria

Inmates must have met the following criteria: 1) Male or female at least 18 years of age, not currently addicted to opioids, but with a diagnosis of opioid dependence and seeking pharmacological treatment, 2) Inmate at one of 4 prisons (3 for males, 1 for females) and eligible for release within 30 days from screening, 3) Capable of understanding and complying with the protocol and has signed the informed consent form (ICF), 4) History of pre-incarceration opiate dependence (DSM-IV-TR) criteria of dependence at the time of incarceration. We used the following to assess pre-incarceration opioid use disorder: 1) Addiction Severity Index (ASI) with time line follow-back (TLFB); 2) MINI International Neuropsychiatric Interview (MINI), Section K; and 3) physical history by study physician), 4) Expressing a goal of opiate-free treatment rather than agonist maintenance upon release, 5) Currently opioid free by self-report, with negative urine drug test for all opioids and no sign of opiate withdrawal following administration of the naloxone challenge and oral naltrexone tolerability assessment, 6) Planning to live in the Baltimore, MD area for at least 8 months following prison release; and 7) Agrees to use an acceptable method of contraception for the duration of the study.

2.1.2. Exclusion criteria

Participants meeting any of the following criteria were excluded from the study: 1) Pregnancy (i.e., positive urine pregnancy test) and/or breastfeeding; 2) Clinically significant active medical condition or observed abnormalities (including: physical examination, laboratory evaluation, and/or urinalysis findings), 3) Active hepatitis or aspartate aminotransferase or alanine aminotransferase >3 times the upper limit of normal, 4) Creatinine above the normal limits, 5) Evidence of hepatic failure including: ascites, bilirubin >10% above upper limit of normal and/or esophageal variceal disease, 6) Past or present history of an AIDS-indicator disease in participants who are infected with HIV, 7) Body Mass Index (BMI) > 40, 8) Any unstable or untreated psychiatric disorder (e.g., untreated psychosis, bipolar disorder with mania), 9) Recent history of suicidal ideation or attempt as assessed by the Sheehan-Suicidality Tracking Scale (S-STS), 10) Current chronic pain diagnosis for which opioids are prescribed or anticipated need for opioid medication during the study period, 11) Current dependence (≤6 months) on any drugs other than prescription opioids or heroin, caffeine, marijuana, alcohol, or nicotine, based on DSM-IV-TR criteria, 12) Positive urine drug test for opioids (including methadone, morphine, buprenorphine), benzodiazepines (unless prescribed), PCP, cocaine, or amphetamines at screening, 12) History of a drug overdose in the past 3 years requiring inpatient hospitalization, 13) Any IM gluteal administration 30 days prior to screening, 14) Participation in a clinical trial of a pharmacological agent within 30 days prior to screening, 15) Known intolerance

Download English Version:

https://daneshyari.com/en/article/328749

Download Persian Version:

https://daneshyari.com/article/328749

Daneshyari.com