CLINICAL TRIAL PROTOCOL - A RANDOMISED, METHADONE-NALOXONE TO METHADONE STANDARD OF CARE IN ADULT OUTPATIENTS WITH OPIOID DEPENDENCE

The Methadone-Naloxone Evaluation Trial

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Development Phase: Therapeutic Use
Investigational Medicinal Product: Methadone-Naloxone

Indication: Opioid dependence
Protocol Version and Date: 1.0 May2019

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Background: Opioid dependence is a chronic disorder that requires long-term treatment and opioid substitution treatment (OST) is the mainstream medical approach to maintain abstinence or to reduce opioid use and its harms. The most commonly used substitute agent is methadone. There is still a need to minimize intravenous use of methadone in a treatment program. The activities of a combined methadone and naloxone in a 50:1 ratio (M&Nx) through oral intake and parenteral administration were tested in a small study group but this needs to be investigated further to identify utility of treatment in clinical settings. This study aims to use M&Nx to increase quality of patient life with enhanced harm reduction.

Concept: This trial intends to study M&Nx in treatment of adult outpatients with opioid dependence in a clinic setting. M&Nx may represent a better approach for patients by offering potential advantages over methadone maintenance alone such as minimising the risks of diversion, injection and selling in the black market.

Primary Objectives: To compare patient satisfaction with M&Nx to methadone alone standard of care in adult outpatients with opioid dependence

Secondary Objectives: To assess treatment effects on illicit, non-prescribed and unsanctioned prescribed use of opioids, on illicit drug use other than opioids, adherence to medication, on quality of life and patient functioning, measures of general physical, mental and psychosocial functioning
treatment related behaviours and perception of treatment opioid withdrawal symptoms diversion and misuse of the trial medications opioid cravings and criminal activity

Method

Medication: Methadone-Naloxone (M&Nx) and standard methadone will both be provided by the Biomed Ltd.

The study will take place in a NSW public hospital-based clinic which does *not* offer regular takeaway doses to patients. The M&Nx subjects *will* have access to 0, 2, 4 or 6 takeaway doses depending on their stability in treatment.

Result: The primary and secondary objectives of the study listed above will be assessed using relevant software and standardised measurement tools and scales.

Conclusion: Opioid prescribing has increased significantly, and diversion of prescribed opioids has become a major problem of drug misuse. The combining M&Nx treatment may reduce the attractiveness of selling, diverting or injecting methadone.

Future: If this pilot study is successfully carried out, a larger multi-centre study would be feasible to allow definitive evaluation of M&Nx in the hospital-based public clinic setting.

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