

METHADONE/NALOXONE THERAPY FOR OPIATE USE DISORDER

A Pilot Study Proposal

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SUMMARY

Methadone remains a primary treatment in the long term management of opioid dependency. There is still a need to minimize the diversion of methadone and its intravenous use. The combination of Methadone and Naloxone (M&Nx) has been tested in a double blind randomized clinical trial (RCT).

This approach needs to be investigated further to identify the utility of treatment in a real life clinic setting. This proposed open-label study aims to use M&Nx to increase the quality of patient life and enhance harm reduction.

INTRODUCTION

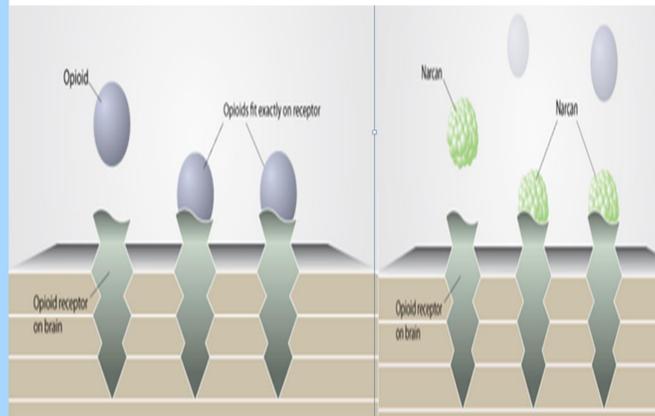
Figure 1 This project has strong commitment the Australian National Drug Strategy¹



Skin and soft tissue infections are the most common cause for hospital admission of injection drug users.² Opioid dependency also contributes significantly to the gap in life expectancy between Aboriginal and Torres Strait Islander people and non-Indigenous people, causing serious harm to the physical and social health of individuals and their communities.³ There is an urgent need to minimize intravenous methadone use and other harm stemming from diversion.

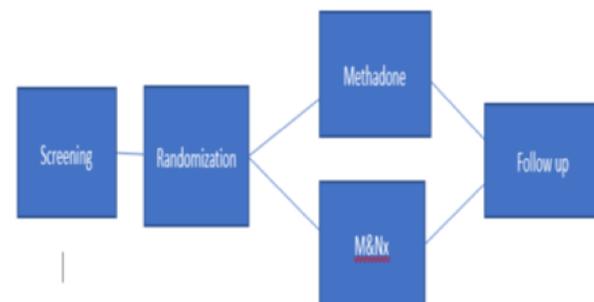
METHOD

Figure 2: Harm reduction. Naloxone is used in opioid overdoses to reverse life-threatening depression of the central nervous system and respiratory system, help patient to able to breathe normally.^{4,5}



Methadone-Naloxone (M&Nx) and standard Methadone trial arms will commence in a NSW public hospital-based clinic for subjects already established on Methadone. The M&Nx subjects will have access to 0, 2, 4 or 6 takeaway doses, depending on stability in treatment.^{6,7}

Figure 3 Trial Flow Chart



RESULTS

Primary Objective	Primary Endpoint
to compare quality of life, self reported diversion and patient satisfaction with Methadone/Naloxone and Methadone alone	Treatment Satisfaction Questionnaire for Medication (TSQM) global satisfaction score Opioid Substitution Treatment Quality of Life Scale (OSTQOL) Self-reported diversion and misuse of the trial medications using (ORBIT)
Secondary Objectives	Secondary Endpoints
To assess patient satisfaction with treatment	TSQM effectiveness score TSQM side effects score TSQM convenience score Patient satisfaction visual analogue scale (VAS)
To assess treatment effects on illicit, non-prescribed and unsanctioned use of opioids	Illicit opioid drug use measured by urine drug screen (UDS) and self-reports of illicit opioid drug use by timeline follow-back method (TLFB)
To assess treatment effects on illicit drug use other than opioids	Illicit drug use measured by UDS and self-reports of drug use by Australian Treatment Outcomes Profile (ATOP)
To assess treatment effects on retention in treatment	Retention in treatment

Figure 4 This project will be help to close the gap in Aboriginal and Torres Strait peoples and non-Indigenous Australians



CONCLUSION

Conclusion

The main hypothesis is that this study will demonstrate that a further multi-center trial is 1, feasible and 2, would be able to assess the value of combining M&Nx in opioid dependency treatment. The pilot data may also show a reduction of the sale, diversion or injection of methadone.

The project covers following 3 priority areas:

- 1-Minimize the harm from Methadone diversion and injection.
- 2-Focus on Australian Indigenous health
- 3- Support the goals of the Australian National Drug Strategy.

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Thanks to WSLHD Drug Health Team

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