A prospective observational study in naturalistic settings to describe long-acting injectable buprenorphine introduction in France: the OBAP cohort study

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INTRODUCTION

Development of long-acting buprenorphine (LAB) for the treatment of opioid use disorder

- Promoting retention and compliance
- Minimizing the risk of misuse
- **France :** Buvidal®

Recommendation to conduct studies under naturalistic conditions and use Patient Reported Outcome Measures (PROMs).

- LAB appears promising for maintaining patients on treatment and improving their quality of life (Deschenau et al. 2022), despite frequent early dropouts (less than 3 months in treatment for 1/3 of patients).
- Therapeutic efficacy in naturalistic conditions yet to be demonstrated

→ **Long-acting Buprenorphine Observatory (OBAP) set up by the University of Bordeaux (SANPSY Lab)**

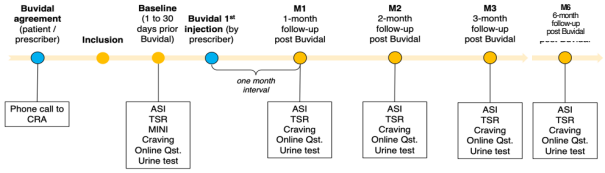
OBAP STUDY: OBJECTIVES

To examine, over a period of 6 months after LAB treatment initiation

- **changes in substance addiction severity**
- **quality of life, craving, opioids and other use and misuse, satisfaction with LAB**

STUDY DESIGN

- **Prospective observational study in France, since March 2023**
- **Adults starting LAB treatment, including patients in prison**
- **Initial assessment before starting LAB treatment, follow-up at 1, 2, 3 and 6 months.**
- **Remote assessments (telephone) with CRA and online questionnaires**



EVALUATIONS

Patient and CRA:

- Information and consent
- Addiction Severity Index interview (ASI)
- Mini International Neuropsychiatric Interview (MINI)
- Craving assessment scale
- Online self-questionnaires : EQ-5D-5L, SF-12, Quality of life (TEAQV), NHP, TSQM
- Urine self-test (posted)

Patient referral for LAB treatment:

- 1 acceptability questionnaire (at the patient's entry into the study)
- 1 acceptance questionnaire (after last follow-up at 6 months)

EXPECTED IMPACTS

Better understand the evolution of patients initiating BAP treatment in terms of quality of life, severity of addiction, treatment adherence

→ **importance for clinical practice and future recommendations**

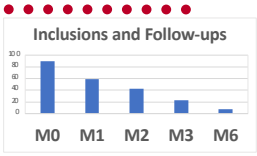
→ **The study is ongoing**

PRELIMINARY RESULTS

INCLUSIONS

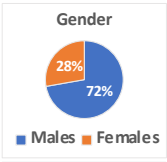
Between March 2023 and April 2024,
156 patients reported, 135 screened
107 eligible, **90** subjects included
Follow-ups: M1: 59 M2: 43
M3: 23 M6: 8

Inclusions and follow-ups are still ongoing



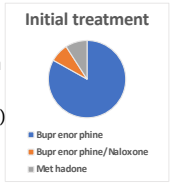
SAMPLE DESCRIPTION

Mean age 45 y.o. (SD=9.8) ; 72.2% Males (n=65)
64.7% (n=71) were housed with someone else
42.2% (n=38) currently employed



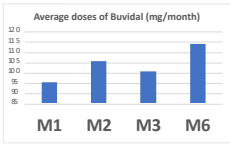
PHARMACOLOGICAL TREATMENTS AT INCLUSION

85.5% (n=77) had a daily treatment for opiate addiction
- Buprenorphine: mean 12.4 mg/day (SD 6.8; n=64)
- Buprenorphine/Naloxone: 13.5 mg/day (SD 9.6; n=6)
- Methadone: 70.7 mg/day (SD 50.0; n=7)



LONG-ACTING BUPRENORPHINE

M1: mean dose 95.6 mg/month (SD 37.0)
M2: 105.8 mg/month (SD 39.7)
M3: 101.0 mg/month (SD24.5)
M6: 114.2 mg/month (SD 25.2)
11 subjects reported stopping buvidal during follow-up. Of these, 3 resumed buvidal treatment



ADDICTION SEVERITY INDEX COMPOSITE SCORES (CS)

Preliminary results showed a significant decrease of ASI CS for alcohol, drugs and tobacco in follow-up compared to basal score

Fields	M0 (N=90) Mean (SD)	M1 (N= 59) Mean (SD)	M1 p-value	M2 (N=43) Mean (SD)	M2 p-value	M3 (N=23) Mean (SD)	M3 p-value
Substances							
Alcohol	0.13 (0.2)	0.09 (0.2)	**2.32^{e-13}** **	0.06 (0.1)	**2.78^{e-10}** **	0.06 (0.1)	**9.88^{e-13}** **
Drugs	0.29 (0.1)	0.13 (0.1)	0.225	0.13 (0.1)	***0.0737*** .	0.08 (0.1)	*0.146*
Tobacco	0.39 (0.3)	0.38 (0.3)	0.921	0.30 (0.2)	**0.0855** .	0.28 (0.3)	0.11
Games	0.02 (0.1)	0.01 (0.1)	0.278	0.01 (0.1)	0.475	0.01 (0.1)	0.317
Medical status	0.27 (0.3)	0.36 (0.4)	0.101	0.36 (0.4)	0.143	0.35 (0.4)	0.282
Employment/support status	0.60 (0.4)	0.58 (0.3)	0.846	0.53 (0.3)	0.354	0.54 (0.4)	0.575
Family & Social relationships	0.13 (0.18)	0.09 (0.2)	0.24	0.09 (0.2)	0.318	0.02 (0.1)	0.513
Psychological status	0.23 (0.2)	0.23 (0.2)	0.977	0.24 (0.2)	0.84	0.20 (0.2)	0.513

SUBSTANCE USE

Significant reduction in opiates and cocaine use at M1, M2, M3 compared to M0 *(days of use in the last 30 days; p <0.05)*

CRAVING

Significant reduction in craving frequency and intensity for opiates (M1, M2, M3) and alcohol (M2) *(craving in the last 30 days; p <0.05)*

PARTICIPER A OBAP

1. Je suis référent (médecin, infirmier) de patients pour lesquels la BAP est prescrite, et intéressé par cette étude afin d'améliorer les connaissances et les retours sur ce traitement. Rejoignez l'étude !

2. Je manifeste mon intérêt auprès de l'équipe de l'étude OBAP
   - Par email : addictologie@u-bordeaux.fr
   - Ou par téléphone : 05 56 56 17 67

   Les ARC de l'étude répondent à mes questions et me font parvenir une procédure résumée, ainsi que des flyers (Une visioconférence peut être organisée si je le souhaite)

3. Lorsque la BAP est envisagée pour un patient, je l'informe qu'un ARC va le contacter par téléphone pour lui expliquer l'étude (5 à 10 minutes)

4. Si accord du patient, je fais parvenir aux ARC OBAP ses coordonnées
   - Par email : addictologie@u-bordeaux.fr
   - Ou par téléphone : 05 56 56 17 67

5. Les ARC OBAP prennent le relai et s'occupent de toutes les démarches liées à l'étude. Je suis informé si mon patient a été inclus. Dans ce cas, les ARC OBAP m'envoient un court formulaire concernant l'acceptabilité de la BAP pour ce patient

Cette procédure peut être adaptée au mieux de vos conditions pratiques. Contactez-nous pour en discuter !

The University of Bordeaux, the promoter of this research, has received funding from Camurus for the operational implementation of the study (agreement n°AST-CT2022-157). The funder is not involved in the conduct of the study. Analysis and publication of the results are the sole responsibility of the promoter, Université de Bordeaux. The study is registered under ID-RCB 2022-A02616-37. It is authorized by the CPP Sud-Méditerranée IV (favorable opinion of 22/02/2023), has been declared MR002 to the CNIL and is insured by Biomedic Insure until 31/12/2024 (n° 2022-A02616-37). ClinicalTrial registration ID NCT06266039.