Trial Description

Title

Addiction recovery of opioid dependent patients treated with injectable subcutaneous depot buprenorphine (BUVIDAL®)

Trial Acronym

ARIDE

URL of the trial

http://www.aride-studie.de

Brief Summary in Lay Language

The aim of this non-interventional treatment study is to evaluate the effects of the injectable depot-buprenorphine (BUVIDAL®) on the quality of life of patients under routine care conditions.
Secondary target criteria are the acceptance of depot-buprenorphine from the patient's point of view, patient satisfaction with the substitution treatment, appropriateness of the buprenorphine dosage from the patient's point of view, further substance use, the psychological burden from the patient's point of view, social participation from the patient's point of view, retention in the treatment with depot-buprenorphine and the cost-effectiveness.
The primary and secondary target criteria are selected to provide an overall evaluation of the addiction rehabilitation (recovery) in opioid addicts in treatment with injectable depot buprenorphine (BUVIDAL®). To control the effects, the primary and secondary targets will be recorded in a matched control group (substitution treatment with other opioids).

Brief Summary in Scientific Language

Only about 2-10% of OST patients in Germany regularly terminate OST with opioid abstinence (Nordt et al., 2004, Wittchen et al., 2011; Zippel-Schultz et al., 2016, Verthein et al., 2017) and the health and social burden of patients remains high even after years of OST (Wittchen et al., 2011; Zippel-Schultz et al., 2016; Strada et al., under review). Given the wide-ranging health and social impact of opioid dependence and the limitation of traditional health parameters to reflect the complexity and severity of the condition, patient-related outcome measures (PROMs) such as quality of life are needed to expand the holistic and integrative approach of OST (Zubaran & Foresti, 2009; DeMaeyer et al., 2010; Laudet, 2011) and to strengthen addiction recovery within OST (White et al., 2012).
The sustained release of the newly approved once-weekly or once-monthly injectable depot buprenorphine formulations (BUVIDAL®) have shown to produce an immediate and sustained opioid blockade and to suppress efficiently opioid withdrawal after the first injection (Haasen et al., 2017; Walsh et al., 2017). A pharmacokinetic evaluation has confirmed clinically relevant plasma concentrations of buprenorphine without daily peaks and therefore the potential benefits of injectable depot buprenorphine in the avoidance of withdrawal symptoms (Albayaty et al., 2017). Accordingly, patients reported a higher acceptability of injectable depot buprenorphine than for the sublingual

formulation (Albayaty et al., 2017).
The long-acting formulation together with pharmacokinetic profiles and the high tolerability and acceptance reported by patients indicate that injectable depot buprenorphine can have beneficial implications on the patients' adherence as well as quality of life (Albayaty et al., 2017). Further, the weekly or monthly administration of injectable depot buprenorphine provides new opportunities for medical and psychosocial interventions towards addiction recovery. This research project is a non-interventional, non-randomized, prospective observational study with control group design. The aim of the study is to evaluate the effects of injectable depot buprenorphine on the quality of life of patients under routine care conditions.

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

The study protocol will be published in an "open access" journal. After publication of the main publication, anonymized data can be made available to other researchers on request ans only for further research purposes. The study group reserves its right to examine applications appropriately and to reject them if necessary.

Organizational Data

- DRKS-ID: **DRKS00020797**
- Date of Registration in DRKS: **2020/03/06**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **PV7078 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F11.2 - Mental and behavioural disorders due to use of opioids; Dependence syndrome**

Interventions/Observational Groups

- Arm 1: **Patients on opioid substitution with injectable depot buprenorphine**
- Arm 2: **Patients on opioid substitution with other approved substitutes. Patients are recruited from the same test centers based on matching criteria (gender, duration of substitution treatment, take-home allocation, GAF score).**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Difference of OSTQOL total score in depot group between baseline (t0) and month 12 (t4)

Secondary Outcome

(1) Quality of life (OSTQOL score) between depot and control group at month 12 (t4); (2) Acceptance (TSQM-14) of injectable depot buprenorphine between months 1 (t1) and Month 12 (t4); (3) Patient satisfaction with OST care (CSQ-8) between depot and control group at t1- t4; (4) Dosage adequacy (ODAS) in depot group at t1-t4; (5) Substance use (i.e. self-reporting) between depot and control group at month 6 (t3) and month 12 (t4); (6) Psychological distress (Mini-SCL) between depot and control group at month 12 (t4); (7) Social participation between depot and control group at month 12 (t4); (8) Retention rate (percentage of patients) in depot group at month 6 (t3) and month 12 (t4); (9) Cost-effectiveness (on the basis of quality-adjusted life years (QALYs); EQ-5D) between depot and control group at month 12 (t4); (10) Changes in quality of life domains (OSTQOL subscales) in depot group between baseline (t0) and month 12 (t4);

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Hamburg**
- Doctor's Practice **Berlin**
- Doctor's Practice **Münster**
- Doctor's Practice **Koblenz**
- Doctor's Practice **Kiel**
- Doctor's Practice **Frankfurt a.M.**
- Doctor's Practice **Wuppertal**
- Doctor's Practice **München**
- Medical Center **Essen**
- Doctor's Practice **Reken**
- Doctor's Practice **Bremen**
- Doctor's Practice **Goslar**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/04/01**
- Target Sample Size: **426**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

(1) Opioid dependence (F11.2) according to ICD-10; (2) Minimum age of 18 years; (3) Ability to follow the study conditions; (4) Signed written informed consent.

Exclusion criteria

(1) Existing contraindications according to the patient's specialist information to use BUVIDAL® (e.g. hypersensitivity to the active substance, severe respiratory failure, severe liver dysfunction, acute alcoholism or delirium tremen); (2) patient already in substitution treatment with BUVIDAL®; (3) Predictable reasons for early dropout (e.g. detention, planned place of residence and change of doctor)

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*