1. **No.**

   FP01909149

2. **Title**

   Clinical Study on Ameliorating Effects of Ifenprodil on Smoking Desire

3. **Period**

   2018-2020

4. **Summary**

Effective pharmacotherapy for nicotine dependence has not been sufficiently established. Ifenprodil is a blocker of G protein-activated inwardly rectifying potassium channels that play a key role in the mechanism of action of addictive substances. We aimed to examine the safety, efficacy, and outcomes of ifenprodil for the reduction of smoking desire in a randomized, double-blind, placebo-controlled trial. The present study was a randomized, double-blind, exploratory, dose-ranging, placebo-controlled, single-center clinical trial. Patients with methamphetamine were randomized into the three arms: placebo, 60 mg/day ifenprodil, and 120 mg/day ifenprodil. Placebo or ifenprodil took orally for 84 days. Follow-up assessments were conducted for 3 months after the drug administration period. The days of abstinence and days of smoking were assessed using the self-reported calendar format based on the Timeline Followback Method. Smoking context is estimated by Fagerstrom Test for Nicotine Dependence with three new questions. This trial was registered in the UMIN clinical trial registry (UMIN000030849; date of registration: January 17, 2018) and jRCT (jRCTs031180080; date of registration: January 15, 2019). Of the 35 participating patients, seven smokers were verified, and statistical analysis could not be performed. Although we did not collect enough smoking participants, a patient who was assigned to the 120 mg/day group felt that smoking was also suppressed during the administration period. In the future, we need to verify the effects of ifenprodil treatment with a large sample size in smokers.