**Aim:** The aim of this trial was to evaluate the safety and efficacy of oral hydration as a substitute for intravenous (IV) hydration after CDDP administration.

**Methods:** The major eligibility criteria included patients with lung cancer, indications for a CDDP-based regimen at a dose of 60 mg/m² or higher, an age of between 20 and 74 years, and adequate renal function. Antiemetic prophylaxis consisted of an appropriate dose of palonosetron, aprepitant and dexamethasone. CDDP was administered after IV pre-hydration with MgSO₄ (8 mEq) and KCL. Five hundred milliliters of commercially available oral hydration solution (OS-1®: Otsuka Pharmaceutical Factory, Inc., Japan) was used as a substitute for IV post-hydration and was administered orally within an hour after CDDP administration. OS-1® contains 50 mEq/L of NaCl, 20 mEq/L of K and 2 mEq/L of MgSO₄. The primary endpoint was the proportion of patients without a grade (G) 2 or higher creatinine (Cr) elevation after the first cycle of chemotherapy. The planned sample size was 46 to reject a proportion of 70% under an expectation of 88% with a power of 90% and an alpha error of 5%.

**Results:** Between May and November 2013, 31 men and 15 women with a median (range) age of 64 (33-74) years were enrolled from three institutions. Of these, 5 received adjuvant chemotherapy, 17 received definitive chemoradiotherapy, and 24 received chemotherapy for advanced diseases. All the patients were able to consume OS-1® within 1 hour without requiring IV post-hydration. The median (range) number of chemotherapy cycles was 4 (3-5). Seven patients received additional IV hydration on day 2 or later, with a median duration (range) of 2 (1-19) days, mainly because of chemotherapy-related anorexia. After the first cycle of CDDP administration, none of the patients experienced a Cr elevation of G 2 or higher, thereby meeting the primary endpoint. Of the 46 patients, 45 (97.8%) completed the CDDP-based chemotherapy without G 2 or higher renal dysfunction. The only patient who experienced a G 2 elevation in Cr (maximum value, 1.97 mg/dL) experienced G 3 chemotherapy-induced diarrhea and exhibited a prompt improvement in the Cr level to 1.11 mg/dL after the resolution of the diarrhea.

**Conclusions:** Oral hydration can be used as a safe and convenient substitute for IV post-hydration for CDDP administration at the standard dose.

**Disclosure:** K. Kubota: Honoraria from TAIHO PHARMACEUTICAL CO., LTD.; All other authors have declared no conflicts of interest.