Appendix A - World Health Organization Trial Registration Data Set

DATA CATEGORY	INFORMATION
Primary registry and trial identifying number	ClinicalTrials.gov NCT03232112
Date of registration in primary registry	20.07.17
Secondary identifying numbers	The Regional Committee on Biomedical Research Ethics (journal number H-17003043), The Danish Data Protection Agency (protocol number RHP-2017-029) and the Danish Medical Agency (EudraCT 2016-003343-11)
Source(s) of monetary or material support	Region Hovedstadens Forskningsfond, Region Hovedstadens Psykiatri and Fonden Novavì. The manufacturer of Bydureon®, AstraZeneca A/S, has no financial interest or involvement in this project.
Primary sponsor	Fonden Novavì
Secondary sponsor(s)	Region Hovedstadens Forskningsfond, Region Hovedstadens Psykiatri
Contact for public queries	Mette Kruse Klausen MD, Psychiatric Centre Copenhagen, Rigshospitalet, Copenhagen University Hospital, Denmark
Contact for scientific queries	Anders Fink-Jensen MD DMSc, Department O (Rigshospitalet), Psychiatric Centre Copenhagen, Copenhagen University Hospital, Denmark
Public title	Does glucagon-like peptide-1 (GLP-1) receptor agonist stimulation reduce alcohol intake in patients with alcohol dependence? Study protocol of a randomized, double-blinded, placebo-controlled clinical trial
Scientific title	Does glucagon-like peptide-1 (GLP-1) receptor agonist stimulation reduce alcohol intake in patients with alcohol dependence? Study protocol of a randomized, double-blinded, placebo-controlled clinical trial
Countries of recruitment	Denmark
Health condition(s) or problem(s) studied	Addiction

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Intervention(s)	2 mg of exenatide prolonged release injection (once-weekly) vs placebo (0.9% saline)
Key inclusion and exclusion criteria	Key inclusion criteria: • Diagnosed with alcohol dependence according to the criteria of ICD-10, World Health Organization and DSM-5 (for the equivalent diagnosis of alcohol use disorder) • Age 18 - 70 years (both included) • Heavy alcohol drinking defined as having alcohol consumption over 60 g of alcohol per day (men) or 48 g of alcohol per day (women) for at least 5 days in the past 30 days prior to inclusion. Key exclusion criteria: • Severe psychiatric or somatic disease • Concomitant pharmacotherapy against alcohol dependence i.e. disulfiram, naltrexone, acamprosate and nalmefene or treatment with any of these compounds within 1 month prior to inclusion
Study type	The present study is a 26-week, double-blinded, randomized, placebo-controlled clinical trial, designed to evaluate the effects of exenatide vs. placebo in 114 patients diagnosed with alcohol dependence.
Date of first enrolment	9th of august 2017
Target sample size	114
Recruitment status	Recruiting
Primary outcome(s)	*The primary endpoint* is percent reduction in total number of heavy drinking days, defined as days with an excess intake of 60/48 grams of alcohol per day (men and women, respectively) the previous 30 days from baseline to follow-up after 26 weeks of treatment, measured by TFLB method.
Key secondary outcomes	The secondary endpoints include changes in total

	alcohol consumption (g/30 days measured by TLFB), changes in number of days without alcohol consumption and PACS score, change in AUDIT score, change in DUDIT score, change in cognitive performance on the SCIP-test, change in the liver parameters gamma-glutamyltransferase (GGT), alanine aminotransferase (ALAT) and PEth. Other parameters will be mean cell volume (MCV), changes in body weight, blood pressure, pulse, overall glycaemic control parameters (HbA1c), kidney function (p-creatinine, eGFR and urine albumin/creatinine ratio) and measures of health (SF-36 and SCL-92).