Baclofen as treatment for relapse in GHB abuse

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24379

Source
NTR

Brief title
Baclofen and GHB dependence

Health condition

Relapse prevention in GHB

Sponsors and support

Primary sponsor: Nijmegen Institute for Scientist-Practitioners in Addiction (NISPA)/ Mental Health Care and Addiction Services (GGZ Nederland)/National program “Scoring Results
Source(s) of monetary or material Support: the Dutch Ministry of Health, Welfare and Sports

Intervention

Outcome measures

Primary outcome

Substance use levels, as indexed by the total number of abstinent days, the duration of continued abstinence after detoxification and level of substance use over a period of 3 months (Timeline Followback).

Secondary outcome

These are:

- Craving levels, as indexed by self report using a visual analogue scale (VAS) and the Desire for Drugs Questionnaire (DDQ) adapted to GHB.

- Psychiatric symptom levels (as indexed by self report Depression, Anxiety and Stress Scale; DASS) and Quality of life (as measured with EQoL-5D).

Study description

Background summary

GHB dependence is a growing health problem in the Netherlands. Attempts to stop using GHB are often followed by relapse in GHB use after successful detoxification. Observations show that craving and loss of control symptoms, associated with GHB dependence, contribute to quick and frequent relapse (two third of the patients within three months after detoxification).

To date management of GHB dependence after detoxification consists mostly of psychosocial treatment without pharmaco-therapeutic support. However, craving for and loss of control over GHB use might also be relieved by pharmaco-therapeutic treatment, as is the case in for example alcohol and heroin dependence. GHB is a GABA-B receptor agonist. The addictive properties of GHB are thought to be mediated by dopamine release in the mesolimbic dopamine circuitry, as is the case in other addictive substances. Baclofen also acts as a GABA-B receptor agonist and due to its specific receptor binding properties, it inhibits dopamine release in the mesolimbic circuitry. This is thought to contribute to its anti-craving properties and beneficial effects on relapse, as observed in alcohol dependent patients. As such, baclofen might be particularly suitable in the treatment of GHB dependence. Indeed, animal data have shown beneficial effects of baclofen on GHB self-administration in mice and there is some anecdotal evidence for beneficial effects on GHB withdrawal in humans.

The aim of the current study is to assess the potential of baclofen as an anti-craving agent in GHB dependent patients. We hypothesize that administration of baclofen to GHB dependent patients after detoxification is associated with reduced levels of craving for and less frequent relapse in GHB use, as compared to treatment as usual (without baclofen), without the occurrence of serious adverse effects.

Study objective

The primary hypothesis is that treatment with baclofen will decrease the risk of relapse in GHB use and increase the duration of abstinence after detoxification in recently detoxified GHB dependent patients

Secondary hypotheses include:

1.treatment with baclofen will contribute to reduced levels of craving for GHB in recently detoxified GHB dependent patients.

2.the use of baclofen at therapeutic levels by recently detoxified GHB dependent patients is well tolerated without major side effects.

3.treatment with baclofen will contribute to recovery form psychiatric co-morbidity in recently detoxified GHB dependent patients.

Study design

Baseline

12 weeks

6 months

Intervention

Patients will receive either baclofen as medication plus TAU or TAU alone. Baclofen will be uploaded over a 2 week period to a maximum of 45-60 mg. Baclofen will be administrated 3 times daily for 12 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

GHB dependence is the primary diagnosis, according to the DSM-IV criteria. Patients are between 18-65 years old and should be able to read and speak Dutch sufficiently

Exclusion criteria

Patients with any current physical or psychiatric safety concerns are excluded.
Exclusion criteria are:

- Presence of a somatic safety concerns. These include liver cirrhosis and impaired renal function (as indicated by aspartate aminotransferase (AST), alanine transaminase (ALT), or gamma-glutamyl transferase (GGT) level >3 times the upper limit of normal (ULN); bilirubin > ULN; serum creatinine > ULN) , unstable hypertension, diabetes mellitus, and seizure disorder, including well controlled cases, currently taking anticonvulsants, insulin, or oral hypoglycemic and pregnancy.

- History or presence of a current psychiatric disorder, including any mood disorder (bipolar disorder or major depressive disorder), any psychotic disorder (including schizophrenia), and/or suicidal ideations.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-02-2014
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4331
NTR-old	NTR4528
CCMO	NL43021.018.12

Study results