Baclofen as treatment for relapse in GHB abuse

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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....

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24379

Bron
NTR

Verkorte titel
Baclofen and GHB dependence

Aandoening

Relapse prevention in GHB

Ondersteuning

Primaire sponsor: Nijmegen Institute for Scientist-Practitioners in Addiction (NISPA)/ Mental Health Care and Addiction Services (GGZ Nederland)/National program “Scoring Results
Overige ondersteuning: the Dutch Ministry of Health, Welfare and Sports

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Baseline

12 weeks

6 months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Toernooiveld 5

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-02-2014

Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten