

# Improving GHB withdrawal with baclofen

<b>Submission date</b> 14/10/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/05/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

GHB (gamma hydroxybutyrate), also known as “liquid ecstasy”, is a widely-used drug. Although it was originally developed as an anaesthetic (sedative), it is often taken recreationally because it is thought to create feelings of relaxation, euphoria and increased libido. GBL (gamma-butyrolactone) is a GHB “prodrug” as it is converted to GBH in the body, causing similar effects. Use of these drugs is more common in groups such as clubbers and the lesbian, gay, bisexual and transgender (LGBT) communities. GHB/DBL can be very addictive if they are used regularly, and users can become dependent on it to function normally. Withdrawal symptoms can be very severe, often causing tremor, sweating, anxiety, agitation and confusion, as well as more serious psychological problems such as delirium and psychosis (losing touch with reality). The current treatment options for people detoxing from GHB/GBL are tranquilizers (benzodiazepines) which help to make people less anxious. In many cases, these drugs are not very effective at combating withdrawal symptoms on their own. One promising alternative treatment approach is to add in a second medication, Baclofen, as it has a calming effect on the brain. The aim of this study is to find out whether prescribing baclofen in addition to a benzodiazepine reduces symptoms during GHB/GBL withdrawal compared to treatment with a benzodiazepine alone.

### Who can participate?

Adults who are detoxing from GBH/GBL

### What does the study involve?

Participants are randomly allocated to be treated with benzodiazepine either with or without baclofen, and are assessed to find out whether this reduces symptoms during GHB/GBL withdrawal.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Addiction Directorate, St. Pancras Hospital (UK)

### When is the study starting and how long is it expected to run for?

September 2015 to July 2017

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Mr Yash Patel

## Contact information

**Type(s)**  
Public

**Contact name**  
Mr Yash Patel

**Contact details**  
Addiction Directorate  
St. Pancras Hospital  
4 St. Pancras Way  
London  
United Kingdom  
NW1 0PE

## Additional identifiers

**EudraCT/CTIS number**  
2013-005319-28

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
18715

## Study information

**Scientific Title**  
Improving GHB withdrawal with baclofen (The GHB Trial)

**Study objectives**  
This feasibility study aims to establish optimal recruitment and assessment to investigate whether prescribing baclofen in addition to a benzodiazepine reduces symptoms during GHB /GBL withdrawal compared to treatment with a benzodiazepine alone.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Dulwich Research Ethics Committee, 10/12/2014, ref: 14/LO/1608

**Study design**

Multi-centre randomised double-blind placebo-controlled clinical trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Topic: Mental Health; Subtopic: Addictions; Disease: Addictions, Addictive Substances– illegal drugs

**Interventions**

Baseline Assessment, Pre-detox assessments - 1 visit; Day 30 assessment, Via telephone call or Face to face; Detoxification visits, Day 1-10 visits; Full written informed consent, Obtained by research team - 20 mins; Follow Up Length: 1 month(s); Study Entry : Single Randomisation only

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Baclofen

**Primary outcome measure**

1. Optimal recruitment rate and strategies is determined at the end of the recruitment period
2. Characteristics of outcome measures are determined at the end of the recruitment period

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

30/09/2015

**Completion date**

31/07/2016

# Eligibility

## Key inclusion criteria

1. Aged 18 years or over who is either:
  - 1.1. In active withdrawal
  - 1.2. Has underlying GHB/GBL dependence and wishes to undergo GHB/GBL detoxification
  - 1.3. Is thought to have underlying dependence and is at risk of acute withdrawal
  - 1.4. Is under the care of a drug treatment service

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

Planned Sample Size: 88; UK Sample Size: 88; Description: The aim is to recruit 88 research participants undergoing GHB/GBL detoxification, 60 planned outpatients and 28 unplanned inpatients.

## Total final enrolment

7

## Key exclusion criteria

1. Clinician does not deem that medication is required for management of GHB/GBL withdrawal.
2. Lacks capacity to consent
3. Unable to take oral medication
4. Unable to take baclofen (according to SPC) due to:
  - 4.1. Known hypersensitivity to baclofen or any of the excipients
  - 4.2. hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
  - 4.3. active peptic ulceration
  - 4.4. porphyria.
5. Unable to follow the study protocol due to serious mental health disorder e.g. enduring psychotic illness, suicidal intent
6. Could be pregnant and refuses a pregnancy test.
7. Taken any investigational drug within 30 days prior to drug administration
8. Where there are "Special warnings and precautions for use" according to the SPC and where risk vs benefit ratio for prescribing is not in favour of prescribing baclofen
9. Has epilepsy not well controlled either with or without medication
10. End stage renal failure (CKD stage 5, GFR <15 mL/min)

## Date of first enrolment

30/09/2015

**Date of final enrolment**

31/07/2016

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Addiction Directorate, St. Pancras Hospital

4 St. Pancras Way

London

United Kingdom

NW1 0PE

## **Sponsor information**

**Organisation**

Central and Northwest London NHS Foundation Trust (UK)

**Sponsor details**

Greater London House

Hampstead Road

London

England

United Kingdom

NW1 7QY

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05drfg619>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	27/09/2016		Yes	No
<a href="#">Basic results</a>			28/05/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No