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Improving GHB withdrawal with baclofen

Submission date
14/10/2015

Recruitment status
No longer recruiting

Registration date
14/10/2015

Overall study status
Completed

Last Edited
28/05/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
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London
United Kingdom
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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 strateries 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?
Protocol article	protocol	27/09/2016		Yes	No
Basic results			28/05/2020	No	No
HRA research summary			28/06/2023	No	No