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Examining a unique medication for alcoholic smokers

Submission date	Recruitment status	[ ] Prospectively registered
15/10/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/10/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/10/2013	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Alcohol and nicotine use frequently happen at the same time and approximately half of the alcoholic population smokes. Spontaneous smoking cessation is infrequent among alcoholics, and up to 75% of alcoholic smokers would require treatment for both dependencies. However, there is presently no approved single treatment that can address both addictions concurrently. The main aim of this study is to investigate if a medication called baclofen may help alcoholic smokers to reduce alcohol and tobacco consumption at the same time.

Who can participate?
Individuals who are heavy drinkers and heavy smokers and dependent on both alcohol and nicotine.

What does the study involve?
The study involves outpatient visits during a four-month period of time. Interested individuals receive a comprehensive medical and psychological screening to make sure they satisfy the required criteria of the study and that it is safe taking the study medication.
Eligible participants are randomly allocated to one of two groups. They are asked to take the study medication (baclofen or a dummy drug called placebo) four times a day for 12 consecutive weeks. They are also asked to come back for outpatient visits once a week during the first month, then once every other week during the second and third month, and finally approximately one month after the medication is stopped for a brief follow-up. At each visit, participants are asked to fill out assessments and they also receive a brief behavioral intervention focused on alcohol- and smoking-related problems.

What are the possible benefits and risks of participating?
Participation to this study may help participants to cut down their alcohol drinking and smoking. The main risks are those associated with the use of a medication, including possible increased sedation, sleepiness, nausea and fatigue.

Where is the study run from?
Participants were recruited via advertisements in public transportation and mass media, referrals from other clinics, and by word of mouth. The study was conducted at Brown University and Roger Williams Medical Center, Providence, RI, USA

When is the study starting and how long is it expected to run for?
The study ran from April 2010 to March 2012.

Who is funding the study?
The study was funded by a non-profit organization called ABMRF/The Foundation for Alcohol Research.

Who is the main contact?
Professor Lorenzo Leggio
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Contact information

Type(s)
Scientific

Contact name
Prof Lorenzo Leggio

Contact details
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02903

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0908000034

Study information

Scientific Title
Examining unique pharmacology intervention for heavy drinking alcohol dependent individuals who smoke

Study objectives
Baclofen, compared to placebo, will improve outcomes of alcohol-tobacco co-use in alcoholic smokers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brown University Institutional Review Board (IRB), November 3, 2009, Study ID 0908000034, Providence, RI.

Study design
Between-subject double-blind placebo-controlled randomized clinical trial (RCT)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Alcohol dependence; nicotine dependence

Interventions
Baclofen 80mg/day (20 mg q.i.d.) versus placebo (contains riboflavin 25mg per each capsule as a marker of compliance and microcrystalline cellulose as filler).

Oral administration, 12-week treatment, 4-week follow-up

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Percent (%) days abstinent from alcohol-tobacco co-use
2. Percent (%) days of alcohol-tobacco co-use

Secondary outcome measures

1. Length of abstinence from alcohol
2. Length of abstinence from smoking
3. Craving for alcohol measured using Alcohol Urge Questionnaire (AUQ) and the Obsessive Compulsive Drinking Scale (OCDS) at screening (week 00), baseline/randomization day (week 01), during the intervention (weeks 02, 03, 04, 06, 08, 10, 12) and the follow-up (week 16).
4. Craving for smoking measured using Questionnaire on Smoking Urges-Brief (QSU-B) and a smoking Visual Analogue Scale (S-VAS) at screening (week 00), baseline/randomization day (week 01), during the intervention (weeks 02, 03, 04, 06, 08, 10, 12) and the follow-up (week 16).

Overall study start date
01/04/2010

Completion date
30/03/2012

Eligibility

Key inclusion criteria
1. Between 18 and 75 years old
2. DSM-IV diagnoses of both alcohol and nicotine co-dependency, with heavy use of alcohol (men ≥ 5 Standard Drink Units [SDUs], and women ≥ 4 SDUs a day) and cigarettes (≥10 cigarettes per day) on average during the last 90 days before screening
3. Interested in receiving treatment for both drinking and smoking (either reducing or stopping both substances; or reducing one substance and stopping the other).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Current (i.e. past year) DSM-IV diagnosis of dependence on any psychoactive substance other than alcohol and nicotine
2. Lifetime DSM-IV diagnosis of schizophrenia, bipolar disorder, or other psychosis
3. Past year diagnosis of major depression, anxiety disorders, eating disorders
4. Risk of suicide (e.g. active plan, or recent attempt in last year)
5. Positive urine drug screen at baseline for any illegal substance other than marijuana
6. Important alcohol withdrawal symptoms, as assessed by a Clinical Institute Withdrawal Assessment for Alcohol revised (CIWA-Ar) score >10

7. History of hospitalization for alcohol intoxication delirium, alcohol withdrawal delirium or seizure
8. Participation in any research study for alcoholism and/or smoking treatment within 3 months prior to signing the consent document
9. Pharmacological treatment with naltrexone, acamprosate, topiramate, disulfiram, nicotine replacement, bupropion, varenicline within 1 month prior to randomization
10. Current use of psychotropic medications or medications that interfere with the metabolism of BACL, history of allergy to BACL or medical contraindications to take BACL
11. Severe medical diseases, such as cancer, cirrhosis, chronic kidney failure, chronic neurological disorders
12. Females who were of child bearing potential and not practicing effective birth control.

Date of first enrolment
01/04/2010

Date of final enrolment
30/03/2012

Locations

Countries of recruitment
United States of America

Study participating centre
121 South Main St
Providence, RI
United States of America
02903

Sponsor information

Organisation
ABMRF/The Foundation for Alcohol Research (USA)

Sponsor details
1122 Kenilworth Drive
Suite 407
Baltimore, MD
United States of America
21204

Sponsor type
Research organisation

Website

http://www.abmrf.org/

ROR
https://ror.org/03pbfnd97

Funder(s)

Funder type
Research organisation

Funder Name
ABMRF/The Foundation for Alcohol Research (USA)

Alternative Name(s)
AMBRF/Foundation for Alcohol Research, Alcoholic Beverage Medical Research Foundation/The Foundation for Alcohol Research

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

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