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Repetitive transcranial magnetic stimulation (rTMS) in cocaine abusers

Submission date
09/05/2015

Recruitment status
No longer recruiting

Registration date
13/05/2015

Overall study status
Completed

Last Edited
16/12/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Cocaine is a highly addictive stimulant drug. Regular users of cocaine are at risk of developing cocaine use disorder (CUD), a common substance abuse disorder linked to numerous health problems. Regular cocaine use, as seen in CUD, has been shown to cause damaging changes to the prefrontal cortex (PFC) brain region. Damage to the PFC leads to loss of inhibitory control. This means affected people are less able to stop themselves from taking drugs, and exhibit what is called 'drug seeking behaviour'. Loss of inhibitory control is an important factor in the development of drug addiction. Despite the numerous problems associated with CUD, no effective pharmacological (drug) or psychological therapies have been developed to successfully treat it. There is some evidence to suggest that a process called repeated transcranial magnetic stimulation (rTMS) of the PFC may help to reduce drug seeking behaviour. rTMS is a noninvasive and relatively painless way to stimulate specific areas of the brain using magnetic fields generated by an electromagnetic coil placed against the head. rTMS is currently used in the treatment of a variety of mood disorders, including depression, with good results. The aim of this study is to see how well rTMS works to reduce drug seeking behaviour in adults diagnosed with CUD.

Who can participate?
Adults diagnosed with cocaine dependency.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention group) are given 8 rTMS treatments once a day for the first five days, then once a week for the following three weeks. Those in group 2 (control group) are given standard daily pharmacological treatment. All participants take part in the study for 29 days. At the end of the 29-days, a 63-day follow-up phase takes place during which participants are offered to continue with the same treatment, or switch to the other treatment. Participants are asked to provide urine samples and answer questionnaires during the study and follow up period.

What are the possible benefits and risks of participating?
All participants receive a treatment for their disease. There is no risk of physical injury or harm associated with participating in this study. Both treatments are well known, and exclusion criteria have been established to reduce any possible side effects.

Where is the study run from?
Hospital of Padova Neurology Clinic (Clinica Neurologica dell'Azienda Ospedaliera di Padova) (Italy)

When is the study starting and how long is it expected to run for?
September 2013 to May 2015

Who is funding the study?
1. Hospital of Padova Neurology Clinic (Clinica Neurologica - Azienda Ospedaliera di Padova) (Italy)
2. Novella Fronda Foundation - ONLUS (Italy)

Who is the main contact?
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Type(s)
Public

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Additional identifiers

Protocol serial number
3165/AO/14

Study information

Scientific Title
Pilot study on reducing the craving for a group of COCAine-dependent patients treated with repetitive transcranial magnetic stimulation (rTMS)

Acronym
COCA

Study objectives
Prefrontal cortex (PFC) stimulation via repetitive transcranial magnetic stimulation (rTMS) might be an effective therapeutic treatment in preventing cocaine use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Clinical Research of the Province of Padova - Padova Hospital (Comitato Etico per la Sperimentazione Clinica della Provincia di Padova – Azienda Ospedaliera di Padova), 05/06/2014, ref: 3165/AO/14.

Primary study design
Interventional

Study design
Between-subject open-label randomised clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cocaine use disorder (CUD)

Interventions
1. Group 1 (intervention group) will be treated with rTMS (MagVenture MagPro 30 model, B-70 Cool coil). The standards used for the stimulation were the following: 15 Hz frequency, impulse intensity equal to 100% of the rMT, 60 impulses per stimulation train, intertrain pause of 15 seconds, 40 stimulation trains, 2400 total impulses for a total duration of 13 minutes.
2. Group 2 (control group) will be treated with a standard protocol used for many years at the Department of Neurology where the study was conducted in Padua, Italy. This protocol includes pharmacological treatment with pramipexole 0.35 mg t.i.d., bupropione 150 mg daily, oxazepam 15 mg t.i.d., triazolam 0.25 mg daily and gamma hydroxybutyrate 1.75 gram daily.

Intervention Type
Device

Primary outcome(s)
Use of cocaine assessed by either positive or negative urine drug screen test for cocaine compared in the rTMS versus control groups.

Key secondary outcome(s)
Craving for cocaine using a 0-10 Visual Analogue Scale.

Completion date
07/05/2015

Eligibility

Key inclusion criteria
1. Diagnosis of current cocaine use disorder (CUD) based on the DSM-5
2. Seeking treatment for cocaine use

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pregnancy
2. Lifetime DSM-5 diagnosis of schizophrenia, bipolar disorder, psychosis or other psychiatric disorders
3. Diagnosis of current alcohol and/or substance use disorder (except for cocaine and smoking) based on the DSM-5
4. Diagnosis of epilepsy/seizure
5. Presence of devices, e.g. pace-makers, cochlear prosthesis, neuro-stimulators, magnetic cochlear prosthesis, intraocular metallic fragments

Date of first enrolment
01/08/2014

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
Italy

Study participating centre
Hospital of Padova Neurology Clinic (Clinica Neurologica dell'Azienda Ospedaliera di Padova)
Outpatient Clinic
Via Giustiniani, 2
Padova
Italy
35128

Sponsor information

Organisation
Hospital of Padova Neurology Clinic (Clinica Neurologica - Azienda Ospedaliera di Padova)

ROR
https://ror.org/04bhk6583

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital of Padova Neurology Clinic (Clinica Neurologica - Azienda Ospedaliera di Padova) (Italy)

Funder Name
Novella Fronda Foundation - ONLUS (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2016		Yes	No