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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?
Prof L Gallimberti
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# Contact information

### Type(s)
Public

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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.

## Study design
Between-subject open-label randomised clinical trial

## 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 contact details to request a participant information sheet.

## 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 measure
Use of cocaine assessed by either positive or negative urine drug screen test for cocaine compared in the rTMS versus control groups.

### Secondary outcome measures
Craving for cocaine using a 0-10 Visual Analogue Scale.

### Overall study start date
01/09/2013

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
32

### 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)

**Sponsor details**
Via Giustiniani, 2
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.sanita.padova.it/reparti/neurologia,1001,35

**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

### Publication and dissemination plan
We plan to disseminate the data (primary and secondary outcomes) in a peer-review Journal. We hope to have a paper accepted for publication by the end of the year.

### Intention to publish date
01/12/2015

### 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 |