

The use of citalopram in treating alcoholic subtypes

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
26/09/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
26/09/2005	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
17/11/2009	Mental and Behavioural Disorders	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

MCT-59634

Study information

Scientific Title

Alcohol use disorders: clinical and biological predictors of treatment outcome

Study objectives

Primary hypothesis:

Initial treatment with citalopram improves early treatment outcome (e.g. reduces early dropouts, increases duration of abstinence, decreases number of drinking days and/or mean number of drinks per drinking day) among alcoholic patients.

Secondary hypotheses:

1. Depression at intake into addiction treatment, as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for a current diagnosis of major depression, is a significant positive predictor of response to citalopram (in terms of drinking-related measures), and a significant negative predictor of overall treatment outcome
2. Abnormal serotonin functioning, as measured by high 5HT uptake in platelets, and the presence of the long variant of the SERT promoter is a significant positive predictor of response to citalopram (in terms of drinking-related measures), and a significant negative predictor of overall treatment outcome

As of 25/03/2009 this record was updated to include an updated anticipated end date; the initial anticipated end date was 30/09/2007.

Ethics approval required

Old ethics approval format

Ethics approval(s)

McGill University Health Centre, Clinical Trials Committee, MUHC - Montreal General Hospital, Montreal, QC gave approval on the 6th September 2002

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Alcohol use disorders

Interventions

Citalopram 40 mg orally (po) once a day (QD) versus placebo for 12 weeks. Both groups receive the standard addiction treatment (weekly individual and group psychotherapy) for 12 weeks.

Trial details received: 12 Sept 2005

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Citalopram

Primary outcome(s)

All planned outcomes are measured at 12 weeks, as follows:

1. Percentage change in number of drinking days
2. Percentage change in mean number of drinks per drinking day
3. Maximum duration of continuous abstinence
4. Percentage change in ASI alcohol/drug composite scores
5. Time spent in treatment (retention)
6. Time to first relapse

Key secondary outcome(s)

All secondary outcomes are measured at 12 weeks:

1. Utilisation of treatment resources (e.g. number of individual/group therapy sessions attended, number of psychiatric appointments, hospitalisation, etc.)
2. Percentage change in number of drinking days
3. Percentage change in depression scores (e.g. Beck Depression Inventory [BDI], Hamilton Rating Scale for Depression [Ham-D], Symptom Checklist [SCL] subscale, etc.)
4. Percentage change in anxiety scores (e.g. Beck Anxiety Inventory [BAI], SCL subscale, etc.)
5. Percentage change in impulsivity scores (e.g. BIS total and subscales)
6. Results of random urine toxicology screening
7. Time to first relapse

Completion date

01/12/2010

Eligibility

Key inclusion criteria

1. Women and men between 18 and 65 years of age
2. Who request treatment at the Addictions Unit
3. Who suffer from alcohol abuse or dependence (as per DSM-IV diagnostic criteria)
4. Who can be contacted reliably
5. Who have signed the consent form (as approved by the local Clinical Trials Committee)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

1. If they currently suffer from another substance dependence, excluding nicotine (as per DSM-IV diagnostic criteria)
2. If they are likely to suffer severe alcohol withdrawal symptoms necessitating hospitalisation (as per American Society of Addiction Medicine guidelines for inpatient alcohol detoxification)
3. If they currently suffer from schizophrenia, schizoaffective disorder, or bipolar disorder
4. If they are currently experiencing psychotic symptoms or suicidal ideation (as determined by clinical interviews by the RA and an Addictions Unit psychiatrist)
5. If they are taking or have taken a serotonergic agent in the two weeks prior to enrolment in the study (four weeks in the case of fluoxetine) e.g. any antidepressant medication, including SSRIs, tricyclic antidepressants, MAO inhibitors, and St. Johns Wort; any mood stabilizer, including carbamazepine, lamotrigine, lithium, and valproate; any antipsychotic medication, including conventional and novel antipsychotics etc.
6. If a female patient is pregnant or breast-feeding - NB women of childbearing potential must be practicing an effective method of birth control while participating in this study, and must agree not to become pregnant during their participation in this study
7. If they have a history of serious adverse reactions or intolerance of selective serotonin reuptake inhibitors (SSRIs)

Date of first enrolment

01/10/2002

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Canada

Study participating centre

McGill University Health Centre

Montreal

Canada

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Sponsor information

Organisation

The Research Institute, McGill University Health Centre (Canada)

ROR

<https://ror.org/04cpvjv19>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-59634)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration