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The use of citalopram in treating alcoholic subtypes

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
389

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
H3G 1B4

Sponsor information

Organisation
The Research Institute, McGill University Health Centre (Canada)

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1650 Cedar Ave, Room S2-214
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Sponsor type
Research organisation

Website
http://www.muhc.ca/

ROR
https://ror.org/04cpxjv19

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

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