

Effect of MIFepristone on COGnitive impairment in alcoholics

Submission date 29/09/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 29/09/2011	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 18/09/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-015837-55

Protocol serial number
9272

Study information

Scientific Title

Glucocorticoid receptor antagonism and cognition in alcoholics

Acronym

MIFCOG

Study objectives

This trial investigates whether treatment with mifepristone reduces cognitive impairment and depressive symptoms in alcohol dependent inpatients undergoing detoxification.

Ethics approval required

Old ethics approval format

Ethics approval(s)

ref: 10/H0808/7

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Addictions; Disease: Addictive Substances alcohol

Interventions

There will be 120 participants, 60 in each treatment group. Mifepristone or placebo will be administered for 14 days starting on the first day of admission. Mifepristone, Adjunctive treatment with mifepristone (600 mg/day for 7 days followed by 400mg/day for 7 days) versus placebo. Cognitive testing will be conducted at the end of treatment. Follow-up contacts will be 3, 6 and 12 months to determine whether each participants has maintained abstinence or relapsed back into alcohol drinking.

Follow Up Length: 12 month(s); Study

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Mifepristone

Primary outcome(s)

Cognitive performance; Timepoint(s): One week after cessation of treatment

Key secondary outcome(s)

Depression symptoms; Timepoint(s): Baseline and weekly for trial duration

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. Diagnosis of alcohol dependence by DSM-IV for at least 5 years
2. Male
3. Aged under 60
4. Willingness to provide informed consent

The study will be limited to males because of the progesterone antagonist properties of mifepristone. The minimum duration of dependence will optimise incidence of cognitive deficits, whilst the upper age limit will minimise the contribution of age-related deficits.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

27

Key exclusion criteria

The following conditions affect HPA function and are common in the alcoholic population:

1. Depressive disorders
2. Smoking
3. Hypertension
4. Obesity
5. Liver disease
6. Kidney disease
7. Post traumatic stress disorder
8. Mental illness
9. Brain damage
10. Comorbid substance dependence

While we shall make the exclusions detailed below, to omit all these disorders would render the majority of the inpatient subject population ineligible, which would affect the external validity of the research and limit the examination of the role of the glucocorticoid Type II receptor. We

therefore propose to include those with less severe forms of these disorders, to document the symptomatology carefully, and to analyze possible influences of these disorders on the variables under study.

Exclusion criteria:

1. Clinical diagnosis of a neuroendocrine disorder
2. Liver damage, determined by alanine aminotransferase (ALT) activity of more than 2.5 x normal range
3. Renal dysfunction
4. Psychotic disorder that would limit valid provision of informed consent (ICD-10 diagnosis from the CIDI)
5. Severe brain damage or severe mental impairment
6. Diagnosis of severe physical illness that would preclude participation (e.g. terminal illness)
7. Inability to understand sufficient english to take understand the information needed for the cognitive testing
8. Female gender
9. Patients with Korsakoff's/Wernicke's syndromes (less than 2% in our Treatment Unit) will not be included because the cognitive deficits are considered to be permanent and due primarily to thiamine deficiency
10. Porphyria
11. Asthma
12. Owing to potential interactions with mifepristone, participants taking the following drugs will be excluded: ketoconazole, itraconazole, metronidazole, miconazole, erythromycin, clarithromycin, troleandomycin, rifampin, rifabutin, norfloxacin, nefadazone, nelfinavir, ritonavir, saquinavir, omeprazole, zafirlukast, fluvoxamine, quinine, phenytoin, phenobarbital, primadone, carbamazepine, troglitazone, amiodarone, warfarin, indomethacin, aspirin, corticosteroids or St John's Wort.

Consumption of grapefruit juice is also contraindicated during mifepristone treatment

Date of first enrolment

01/10/2011

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

St George's, University of London

London

United Kingdom

SW17 0RE

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/09/2020	18/09/2020	Yes	No
Protocol article	protocol	24/02/2016		Yes	No
Basic results			28/05/2020	No	No

