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Effect of MIFepristone on COGnitive impairment in alcoholics

Submission date	Recruitment status	[X] Prospectively registered
29/09/2011	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/09/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2020	Mental and Behavioural Disorders	

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

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

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, metronodazole, 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

HRA research summary	28/06/2023	No	No