

Effect of MIFepristone on COGnitive impairment in alcoholics

Submission date
29/09/2011

Recruitment status
No longer recruiting

Registration date
29/09/2011


Overall study status
Completed


Last Edited
18/09/2020

Condition category
Mental and Behavioural Disorders


 Prospectively registered

 Protocol added

 SAP not yet added

 Results added

 Raw data not yet added

 Study completed

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

2009-015837-55

IRAS number

ClinicalTrials.gov number

Protocol/serial number

9272

Study information

Scientific Title

Glucocorticoid receptor antagonism and cognition in alcoholics

Acronym

MIFCOG

Study hypothesis

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2011

Overall study end date

31/12/2014

Eligibility**Participant 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

Age group

Adult

Sex

Male

Target number of participants

Planned Sample Size: 120; UK Sample Size: 120

Total final enrolment

27

Participant 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 and 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

Recruitment start date

01/10/2011

Recruitment end date

31/12/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St George's, University of London

London

United Kingdom

SW17 0RE

Sponsor information

Organisation

King's College London (UK)

Sponsor details

Institute Of Psychiatry

16 De Crespigny Park

London

England

United Kingdom

SE5 8AF

Sponsor type

University/education

Website

<http://www.kcl.ac.uk/>

ROR

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

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/02/2016		Yes	No
Basic results			28/05/2020	No	No
Results article	results	16/09/2020	18/09/2020	Yes	No
HRA research summary			28/06/2023	No	No