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Drug treatment for depression in patients undergoing haemodialysis

Submission date
01/05/2014

Recruitment status
No longer recruiting

Registration date
01/05/2014

Overall study status
Completed

Last Edited
28/10/2019

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
End Stage Renal Disease (ESRD) is the complete or almost complete failure of the kidneys to function. Dialysis or kidney transplantation are the only treatments that can help patients with this condition. In addition, these patients need to take a range of medicines, such as for blood pressure control, anaemia, and bone and mineral management. Haemodialysis (HD) is the most common dialysis treatment, and usually involves lengthy out-patient treatment sessions three times a week, placing significant burdens on the patient and their family or carers. A small number of patients can administer dialysis at home. A large proportion of ESRD patients suffer from depression (about 20%) which impairs quality of life (QoL), reduces their capacity to manage their own medications, increases the risks of other illnesses, and reduces life expectancy. In addition, many ESRD patients also suffer from poor energy levels and tiredness, and we are interested in how these symptoms relate to depression. Effective treatments, both psychological and drug-based, exist for moderate to severe depression. Effective drugs include Selective Serotonin Reuptake Inhibitors (SSRIs). ESRD patients have unique medical and psychological pressures, and it is unclear whether a SSRI is helpful for this group of patients. There are a very small number of limited studies in patients with this condition, so we do not know whether a SSRI is effective, whether there may be additional side effects, or even whether ESRD patients with depression would wish to take additional medication, such as a SSRI. The aim of this study is to examine these issues to allow us to work out the practicability of undertaking a larger study to formally answer these questions.

Who can participate?
Adults aged 18 or over with ESRD and receiving haemodialysis.

What does the study involve?
The study is split into three phases. Phase one will evaluate the number of ESRD patients who are diagnosed with depression. Phase two will assess the feasibility of conducting a drug trial in this group of patients by assessing the number who take part and evaluating their outcomes including the safety of sertraline in ESRD patients. Phase three will explore the patient experience of participating in a trial and taking additional medication. Participants will be randomly allocated to receive either sertraline (a licensed SSRI) or a placebo (dummy) drug. They will remain on the study medication and followed up for 6 months.

What are the possible benefits and risks of participating?
Firstly, we will be able to tell you if you suffer from depression. Secondly, you will have the opportunity of joining the clinical trial. We cannot promise the trial will help you, but if you receive treatment with sertraline your mood may improve. You will have extra contacts with the nursing and medical staff including the psychiatrist throughout the study period of 6 months, who will monitor you carefully. You will be asked questions about your mood by the psychiatrist and by completing questionnaires. Occasionally these questions can be a bit upsetting so it is important to remember that you do not have to answer any questions you do not want to. We cannot promise the trial will help you. You will not know if you are taking sertraline or the placebo. This means that you could feel better but you could also feel worse and your depression may get worse.

Where is the study run from?
East and North Herts NHS Trust and the University of Hertfordshire (UK)

When is the study starting and how long is it expected to run for?
April 2013 to February 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Ken Farrington
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Contact information

Type(s)
Scientific

Contact name
Prof Ken Farrington

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Additional identifiers

EudraCT/CTIS number
2012-000547-27

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
14560

Study information

Scientific Title
A pilot randomised controlled trial of drug treatment for depression in patients undergoing haemodialysis

Acronym
ASSertID (A Study of Sertraline in Dialysis) Phase 2

Study objectives
The main research question is to evaluate the feasibility of conducting a randomised, double-blind, placebo-controlled pilot trial in patients with End Stage Renal Disease and depression. The treatment under investigation is Sertraline, a licensed SSRI. The study is split into three phases. Phase one will evaluate the number of ESRD patients who score as depressed on the BDI-II and PHQ9, and fatigued on the SF-36 and MFI. Phase two will assess the feasibility of conducting a randomised drug trial in this group of patients, by measuring the number who take part and evaluating their outcomes as well as looking at the safety and drug exposure of Sertraline in ESRD. Phase three will explore the patient experience of participating in this trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Bentham, 01/11/2012, ref: 12/LO/1554

Study design
Pilot double-blind parallel-group placebo-controlled randomised trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details provided in the Interventions field to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Mental Health, Renal disorders; Subtopic: Depression, Renal disorders; Disease: Depression

Interventions
The main research question is to evaluate the feasibility of conducting a randomised, double-blind, placebo-controlled trial in patients with ESRD and depression. The treatment under investigation is sertraline, a licensed SSRI. The study is split into three phases. Phase one will evaluate the number of ESRD patients who score as depressed on the Beck Depression Inventory. Phase two will assess the feasibility of conducting a randomised drug trial in this group of patients by assessing the number who take part and evaluating their outcomes including the safety and drug exposure of sertraline in ESRD patients. Phase three will explore the patient experience of participating in a trial and taking additional medication. This is a pilot study looking at running a phase IV, double-blind, placebo-controlled, randomised trial with two arms (sertraline hydrochloride versus placebo). A block randomisation on a web-based programme has been prepared by Norwich CTU. Patients will be starting on the study medication 50 mg orally per day for 2 months, with the option of stepping up to 100 mg orally for the remainder of the trial, if clinically indicated. Patients will remain on the study medication and followed up for 6 months.

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Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sertraline

Primary outcome measure
The primary outcome measures relate to the feasibility of conducting a large-scale randomised controlled trial. The aim is to characterise:
1. The proportion of eligible patients
2. The extent to which patients refuse to take part
3. The number who complete the study

Secondary outcome measures
The secondary aims are to assess the acceptability of and adherence to the study treatment, to assess how missing data biases the study outcomes, and to record the reported adverse events and safety of the study treatment in this group of patients

The analysis will estimate the variability in BDI, MFI, SF-36 energy/fatigue subscale, PHQ-9, MADRS, KDQoL and EQ5D scores.

Overall study start date
15/04/2013

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Screening eligibility:
1.1. Patients with ESRD and receiving haemodialysis. They will have started dialysis at least 3 months ago and have continued to receive dialysis in the past 3 months prior to the invitation to take part in this study
1.2. Adults aged 18 or over
1.3. Patients who speak and read English sufficiently well to complete questionnaires
2. Trial eligibility:
2.1. Patients with a Beck Depression Inventory (BDI-II) of 16 or above
2.2. Patients who, according to the CI/PIs, have a prognosis of more than 1 year
2.3. Patients with a diagnosis of mild to moderate Major Depressive Disorder according to a Diagnostic and Statistical Manual of Mental Disorders (DSM) IV interview conducted by a research psychiatrist
2.4. Patients who score 18 or above on the Montgomery-Asberg Depression Scale (MADRS)
2.5. Patients who have the mental capacity to understand the trial and are able to give consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Patients who are currently being or have been treated for depression and/or anxiety with any antidepressants in the last 3 months
2. Patients who are currently being or have been treated for depression and/or anxiety with a formal psychological therapy in the last 3 months
3. Patients who are awaiting a planned living donor transplant within the period of the trial
4. Patients who have less than 1 year survival prognosis according to the nephrologist

5. Patients for whom Sertraline is contraindicated by their existing drug regimen according to the Summary of Product Characteristics
6. Patients with hepatic impairment, whose serum level of alanine transaminase (ALT) is two times the upper limits of normal or higher
7. Patients who have hepatitis B or hepatitis C, HIV/AIDS, and/or Creutzfeldt-Jakob disease
8. Patients who are pregnant or of childbearing potential who are not using adequate contaception
9. Patients who are or have been involved in an intervention study in the last 3 months
10. Patients with impaired coagulation judged by an international normalised ratio (INR) greater than 1.3
11. Patients who are currently taking MAOIs or pimozide
12. Patients who are currently taking triptans, antipsychotics, dopamine antagonists, tramadol, linezolid and warfarin
13. Patients with a diagnosis of a severe Major Depressive Disorder
14. Patients at moderate to severe risk of self-harm according to the assessment of the study psychiatrist
15. Patients who score above 4 on item 10 on the MADRS
16. Patients who answer yes to question A3G on the Mini-International Neuropsychiatric Interview (MINI)
17. Patients who have other known psychiatric conditions, including substance misuse, psychosis, or personality disorder, dementia or panic disorder, with the exception of other anxiety disorders (for example GAD or OCD)

Date of first enrolment
15/04/2013

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lister Hospital
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Sponsor information

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Sponsor type
University/education

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Sponsor details

Sponsor type
Not defined

ROR
https://ror.org/02ryc4y44

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB) (UK); Grant Codes: PB-PG-0110-21073

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	26/10/2015		Yes	No
Results article	results	07/02/2017		Yes	No
Results article	results	05/01/2018		Yes	No
Results article	results	05/01/2018	28/10/2019	Yes	No
HRA research summary			28/06/2023	No	No