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Testing a new stepwise strategy for the management of renal anaemia

Submission date
28/01/2015

Recruitment status
No longer recruiting

Registration date
29/01/2015

Overall study status
Completed

Last Edited
29/01/2015

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anaemia is a condition where a lack of iron in the body results in a lower than usual number of red blood cells. This means that there isn't as much oxygen being delivered to the organs and tissues. This can cause a number of problems, including tiredness, breathlessness, heart palpitations and even heart failure. Anaemia is common in people with chronic kidney disease (CKD) and is associated with poor health outcomes. This study aims to develop and test a step-wise model of intervention for treating anaemia in people with CKD in primary care. It is hoped that this treatment model will improve the health of people with CKD and anaemia.

Who can participate?
General practitioners (GP) and also adult CKD patients with anaemia.

What does the study involve?
The study has two phases.
In phase 1, GPs and patients are invited to take part in group discussions in order to explore what difficulties there are in managing anaemia in CKD patients and how best to run phase 2.
In phase 2, GP practices are randomly allocated into one of two groups. Those in group 1 (usual practice), treat their patients as usual. Those in group 2 (intervention) treat their patients according to the step-wise model of intervention. This includes confirming diagnosis, taking simple steps to improve the patients' condition (such as stopping medications that may cause bleeding), giving patients iron tablets and, if their condition warrants it, intravenous iron or erythropoiesis-stimulating agents (medication that stimulates the production of red blood cells). Health outcomes for all participants are measured at the start of the study, 6 months later and then after a year.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
GP practices in the UK

When is the study starting and how long is it expected to run for?
September 2014 to February 2017

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

Who is the main contact?
Dr Tom Chan

Study website
http://www.clininf.eu/projects/renal-anaemia.html

Contact information

Type(s)
Scientific

Contact name
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Contact details
University of Surrey
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17012

Study information

Scientific Title
Testing a new stepwise strategy for the management of renal anaemia in primary care: an exploratory cluster randomised trial

Study objectives
This study aims to develop and evaluate a step-wise model of intervention for treating anaemia in people with chronic renal disease (CKD) in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC approval date 18/07/2014, ref: 14/LO/1185

Study design
Randomised; Interventional and Observational; Design type: Process of Care, Cohort study

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 contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Other Primary Care; Disease: All Diseases

Interventions
1. Phase 1:
Systematic review. Focus Group discussions:
1.1. Practitioners groups
1.2. Patients groups
Test data extraction tools & methods
2. Phase 2:
Cluster randomised trial of step-wise anaemia interventions in CKD

Intervention Type
Mixed

Primary outcome measure
The proportion of people with CKD who remain anaemic one year after entry into the study

Secondary outcome measures
Feasible and acceptable step-wise model of interventions for Phase 2

Overall study start date
01/09/2014

Completion date
28/02/2017

Eligibility

Key inclusion criteria
Phase 1: In-depth discussion
Practitioners and patients from four GP practices will be invited to take part in the in-depth discussions. These four GP practices will be purposefully selected on the following criteria:
1. Achievement of Quality Outcome Framework (QOF) points for CKD
2. At least the national average of people aged over 65 years (as CKD particularly affects older people)

Phase 2: Clustered Randomised Trial
Practice level:
1. GP Practices should be computerised and have had the same computer system for at least 3 years; they should have had laboratory-links (ensuring completeness of pathology results) for this period; and a practice computer system using 5-byte Read codes (commonest used in UK), or Clinical Terms Version 3 (CTv3).
2. Practices have space for the review clinic and consent to participate.
Patient level:
1. Adult patients registered with participating practices with CKD (stage 3 and 4) and anaemia (Hb=11g/dl), who are not under the care of a renal physician, and without an obvious other cause for their anaemia (i.e. overt cause of blood loss)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24; Description: The study will recruit 4 GP practices for diagnostic analysis in Phase 1 and 20 GP practices the cluster randomised trial in Phase 2 (a total of 24 GP practices).

Key exclusion criteria
Practice level:
1. Practices with plans to change computer systems during the proposed 3-year study
2. Practices involved in the in-depth group discussions at Phase 1 will be excluded from taking part in Phase 2.
Patient level:
1. Patient under 18 years of age
2. Those unable to consent
3. Those receiving dialysis or who have had a renal transplant
4. Those with previous adverse reaction to iron
5. Those currently or previously treated with erythropoietin
6. Those who have expressed a wish to opt out of sharing electronic records to their GP (identifiable by the present of an 'Optout Read codes': 93C1, or 'Refused consent for upload to local shared electronic record': 9Nd1 in the GP information systems).

Date of first enrolment
01/09/2014

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
School of Management
Guilford
United Kingdom
GU2 7XH

Sponsor information

Organisation
Guildford and Waverley CCG

Sponsor details
Dominion House
Woodbridge Road
Guildford
England
United Kingdom
GU1 4PU

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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?
HRA research summary			26/07/2023	No	No