

Testing a new stepwise strategy for the management of renal anaemia

Submission date 28/01/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/01/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/01/2015	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact information

Type(s)
Scientific

Contact name
Dr Tom Chan

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

University of Surrey

School of Management

Guilford

United Kingdom

GU2 7XH

Sponsor information

Organisation

Guildford and Waverley CCG

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes