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Feasibility pilot of anticoagulation self-testing

Submission date
09/05/2018

Recruitment status
No longer recruiting

Registration date
26/11/2018

Overall study status
Completed

Last Edited
26/11/2018

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
Warfarin is a drug that prevents blood clotting. It is prescribed to people who have illnesses caused by blood clots, such as stroke, heart attack and deep vein thrombosis. It is important to get the dose of warfarin right, so that it stops harmful blood clots, but does not prevent blood clotting when needed, for example from a cut. This means that people who take warfarin must have regular checks of the time taken for their blood to clot. This is called an INR test. Patients usually have to go to the GP or another clinic to have the blood test. This study will test whether people can use a machine at home to do accurate INR tests and whether they prefer to do the test at home rather than to go in to a clinic or GP surgery.

Who can participate?
Adults taking warfarin long-term.

What does the study involve?
Participants on long term warfarin receive a home INR testing machine. Participants receive training on how to use the machine and perform self testing at home. This involves taking a small drop of blood.
The trial will last for 6 months and involves up to 4 visits to the GP surgery. Visit 1 involves providing further information about the study to participants who have expressed an interest in participating and receiving their consent if they are eligible and wish to participate.
Visit 2 (baseline visit) is a training session for the participants, who are then given a self testing machine. Participants also receive a questionnaire that explores their thoughts about INR self testing. For the next month participants are asked to test their INR weekly using the machine at home and telephone in their results to the GP clinic. Participants are then called back by the GP Practice Nurse who will advise them on the warfarin dose they should take and INR testing instructions. If the INR is stable and it is safe for the participant to test less frequently, during month 2 participants may go to self testing every fortnight. If clinically safe, participants may go to self testing monthly in month 3.
At 3 months, participants have a face-to-face research visit at the GP practice to enable their home INR machine to be compared to the GP INR machine to check its accuracy. During the remaining months in the trial, participants may test monthly depending on their clinical needs. Home INR testing frequency may vary depending on clinical need.
At the end of the study (6 months) participants have a face-to-face appointment where their home INR machine is checked against the GP INR machine and to complete a participant

questionnaire exploring their thoughts about INR self testing. Participants are also asked to complete a second questionnaire called a self-reported measure which also asks participants about their involvement in the study and the training they received on their home INR machine. At the end of the study, participants can keep their home INR testing machine.

What are the possible benefits and risks of participating?
INR self-testing is a safe procedure. Participants will receive thorough training before starting the trial. The training includes how to safely obtain a blood sample, safe disposal of equipment (for example the sharp tool (lancet) used to break the skin and use of a sharps bin) and how to use and maintain the machine. There are no significant risks in taking part in this study. The research team are available at all times to answer any concerns or queries.
Participants may find that being able to self test from home and report INR readings to the surgery via telephone is less time-consuming and burdensome. Participants may find this approach to anticoagulation (blood clotting) testing to be empowering and help them understand their condition better.

Where is the study run from?
Betsi Cadwaladr University Health Board (Wales)

When is the study starting and how long is it expected to run for?
February 2017 to December 2018

Who is funding the study?
Betsi Cadwaladr University Health Board

Who is the main contact?
Judith Colclough, Judith.Colclough@wales.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Judith Colclough

Contact details
Betsi Cadwaladr University Health Board
Ysbyty Glan Clwyd
Bodelwyddan
United Kingdom
LL18 5UJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
220395

Study information

Scientific Title
A feasibility study investigating the operational practicability and acceptability of home International Normalised Ratio (INR) self testing in patients receiving long term warfarin.

Study objectives
1. To determine whether INR (International Normalised Ratio) self testing is practical for patients and to establish the acceptability of self testing and any presently unforeseen challenges.
2. To pilot the feasibility of self testing INRs by patients at a large Primary Care Centre.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 5 Bangor, 02/03/2017, 17/WA/0052

Study design
Single-centre feasibility/pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Long term anticoagulation therapy

Interventions
There is one study arm therefore no randomisation. Participants receive a home INR testing machine (Coagucheck XS Machine) and are asked to test their INR using a small blood test and telephone their results to the practice research nurse in the following frequencies over a 6-month period. The participants are called back by the research practice nurse with dosing instructions and when to perform the next INR test :
Month 1: weekly

Month 2: fortnightly
Months 3-6: monthly
However the frequency of testing is subject to variability and clinical need and is tailored to the individual. Therefore the frequency of home testing may vary between participants. Each INR result will inform the required testing INR frequency and the recommended warfarin dose titration post testing.

The participant's home INR machine is calibrated (INR testing performed on home INR testing machine and checked against the GP practice machine) during the baseline visit, at 3 months and during the end-of-study visit (6 months).

Participants also complete a baseline questionnaire at 0 months and at the end of the study (6 months) which explores the participant's feelings around INR testing. At the end of the study participants are also asked to complete a short self-report to explores the participant's feelings around INR testing and their participation in the research.

Intervention Type
Device

Primary outcome measure
1. Time in Therapeutic Range (TTR, a recognised measure of warfarin prescription efficacy in clinical practice) is calculated using specialised software called INRStar at 0, 3 and 6 months.
2. Participant experience and acceptability and usability of the INR self-testing machine is assessed by a self-reported questionnaire at 6 months

Secondary outcome measures
Participant empowerment to self-monitor and better understand their condition is assessed via questionnaire at baseline and at 6 months.

Overall study start date
28/02/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. On long-term warfarin
2. Aged 18 years or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Any individual without capacity to consent to partaking in the pilot e.g. dementia
2. Antiphospholipid syndrome
3. Receiving end-of-life care

Date of first enrolment
15/06/2017

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Clarence House Medical Centre
West Kinmel Street
Rhyl
United Kingdom
LL18 1DA

Sponsor information

Organisation
Betsi Cadwaladr University Health Board

Sponsor details
Research and Development Department
Ysbyty Gwynedd
Penrhosgarnedd
Bangor
Wales
United Kingdom

LL57 2PW
+44 (0)1248 384877
Lynne.Grundy@Wales.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.betsiresearch.wales.nhs.uk/home

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Betsi Cadwaladr University Health Board

Results and Publications

Publication and dissemination plan
We plan to publish the research findings in a high-impact peer reviewed journal within one year of end of study.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
Research data will be held by the custodian for the data, the Chief Investigator Judith Colclough. The results of the trial will be made available in line with our report and dissemination plan outlined on our ethics application.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No