

# Feasibility pilot of anticoagulation self-testing

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/11/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/11/2018	<b>Condition category</b> 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

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](mailto:Judith.Colclough@wales.nhs.uk)

## Contact information

**Type(s)**

Scientific

**Contact name**

Mrs Judith Colclough

**Contact details**

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## 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

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**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No