

Pharmacy pilot to detect hypertension and atrial fibrillation

Submission date 27/03/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/04/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/06/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English Summary

Background and study aims

Hypertension or high blood pressure usually has no symptoms. It is detected by measuring a person's blood pressure. If the blood pressure is too high, it can put the person at risk of heart disease and stroke. Finding out if you have high blood pressure means that it can be treated by your doctor, thus reducing the chances of you having heart disease or stroke. Atrial Fibrillation, also known as A. Fib or AF, is the most common arrhythmia. An arrhythmia is an abnormal heart beat which is continuously irregular with no pattern to it at all. It can affect adults of any age but is more common as you get older. With atrial fibrillation, your heart beats in a disorganised and irregular way which can lead to a range of symptoms and potential complications. The aim of this study is to provide a health check and heart health information service to people 50 years of age and over to determine the proportion of people in this group who have either high blood pressure or atrial fibrillation or both.

Who can participate?

Adults 50 years of age and over who have no previous history of heart disease, atrial fibrillation or stroke.

What does the study involve?

The pharmacist will measure the participant's blood pressure and pulse. Participants will be given a written copy of their results along with advice and leaflets to help them improve their lifestyle. If the results are above a certain level, the pharmacist will advise the participant to see their GP and have further tests. Participants will also be asked to complete a short survey about what they thought of the health check. If the participant is referred to their GP, the pharmacist will phone them after a few weeks to see what happened when they saw their GP. The participant's part in the study will take about 20-30 minutes.

What are the benefits and risks of participating?

Participants will find out what their blood pressure and pulse readings are. If their results are above a certain level, the pharmacist will advise them to see their GP and have further tests. Having high blood pressure or atrial fibrillation diagnosed and controlled reduces the chances of having heart disease or stroke in the future. There are no foreseeable risks attached to taking part in this study.

Where is the study run from?

The study is coordinated by the Irish Pharmacy Union in Dublin, Ireland and run in community pharmacies across Ireland.

When is the study starting and how long is it expected to run for?

January 2018 to October 2018 (as of 04/10/2018)

Who is funding the study?

1. Pfizer Health Ireland (Ireland)

2. Irish Pharmacy Union (Ireland)

Who is the main contact?

Pamela Logan

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Contact information

Type(s)

Public

Contact name

Ms Pamela Logan

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IPU2

Study information

Scientific Title

Irish Pharmacy Union (IPU) Pilot to Detect Hypertension and Atrial Fibrillation: to provide a health check and heart health information service to people 50 years of age and over to determine the proportion of people in that cohort with hypertension and/or atrial fibrillation.

Study hypothesis

To determine the proportion of people 50 years of age and older with hypertension and/or atrial fibrillation

Ethics approval required

Old ethics approval format

Ethics approval(s)

National University of Ireland (NUI) Galway Research Ethics Committee, 07/06/2018, 18-May-15

Study design

Cross-sectional cohort study. We aim to recruit 50 community pharmacies across Ireland to participate in the pilot. Participating pharmacies will display posters asking people aged 50 years and over to participate in the health check pilot. Each pharmacy will be asked to recruit 20 people, giving a total of 1,000 pilot participants. The pharmacist will measure the patient's blood pressure and pulse and depending on the result, give lifestyle advice or refer to GP.

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Condition

Hypertension and atrial fibrillation

Interventions

The pharmacist will measure the person's blood pressure, according to the Irish Heart Foundation SOP, and measure the person's pulse, using the Kardia Mobile device. Results will be recorded on IPUnet (a secure web-based platform). Depending on the results, people will be offered lifestyle advice or counselling or repeat health check as appropriate and referred to their GP, if considered necessary, using Irish Heart Foundation referral criteria outlined in the SOPs. The outcomes will be recorded on IPUnet. People who are referred to the GP will receive a phone call from the pharmacy a few weeks later to see if they were diagnosed, prescribed a medicine or referred for further tests. Such details will be recorded on the person's IPUnet record. All participants who take part in the pilot will receive lifestyle advice from the pharmacist and be given copies of the Irish Heart Foundation leaflets on Manage Your Blood Pressure and AF & You. People who undergo the health check will be asked to complete a survey with the pharmacist at the end of their health check to assess their acceptability of the service. Details of the survey will be recorded on IPUnet. Pharmacists will be required to complete an online survey at the end of the pilot to determine acceptability of the service, the reasons for

success or lack of success and the feasibility within the service delivery environment. The intervention for the patient should take around 20-30 minutes plus follow-up phone call if necessary.

Intervention Type

Other

Primary outcome measure

From the anonymised and aggregated data recorded on IPUnet:

1. Percentage of patients referred to GP with high blood pressure or high pulse rate. Referral will be decided using criteria devised by the Irish Health Foundation.

Secondary outcome measures

From the anonymised and aggregated data recorded on IPUnet:

1. Proportion of patients by age and gender
2. Average blood pressure measurement
3. Average pulse measurement
4. Type of advice provided per cohort (i.e. lifestyle advice only or referral to GP)
5. Outcome of referral to GP

Overall study start date

17/01/2018

Overall study end date

31/10/2018

Eligibility

Participant inclusion criteria

1. 50 years of age and over
2. No previous history of cardiovascular disease, atrial fibrillation, TIA, stroke;
3. People who are receiving treatment for hypertension or diabetes will be included to see if they have atrial fibrillation.

Participant type(s)

All

Age group

Adult

Sex

Both

Target number of participants

1000

Participant exclusion criteria

1. People under 50 years of age;
2. People with history of cardiovascular disease, atrial fibrillation, TIA, stroke;
3. People under the care of psychiatric services;
4. People not able to participate in the study due to language difficulties.

Recruitment start date

06/07/2018

Recruitment end date

31/08/2018

Locations

Countries of recruitment

Ireland

Study participating centre**Irish Pharmacy Union**

Butterfield Avenue, Rathfarnham

Dublin

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Sponsor information

Organisation

Irish Pharmacy Union

Sponsor details

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Sponsor type

Other

Website

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ROR

<https://ror.org/048q77b60>

Funder(s)

Funder type

Not defined

Funder Name

Pfizer Healthcare Ireland

Funder Name

Irish Pharmacy Union

Results and Publications

Publication and dissemination plan

We intend to publish the results of the pilot and make it available to the Department of Health and Health Service Executive, as well as all community pharmacies.

All data collected by pharmacists will be inputted onto a web-based platform. The researcher will only have access to aggregated and anonymised data, but not individual patient data.

2018 results published online in <https://ipu.ie/wp-content/uploads/2014/11/IPU-Pilot-to-Detect-Hypertension-and-Atrial-Fibrillation-Report-2018.pdf>

25/06/2019: No publications are planned as of 20/06/2019

Intention to publish date

07/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/12/2018	11/01/2019	No	No