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Pharmacy based screening of high risk individuals using stepwise methods

Submission date
09/01/2014

Recruitment status
No longer recruiting

Registration date
20/02/2014

Overall study status
Completed

Last Edited
31/10/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The prevalence of diabetes has risen dramatically in recent years. It is estimated that there are up to half a million people in the UK who have undiagnosed diabetes and this figure is expected to rise. People with undiagnosed diabetes are at a higher risk of problems with the eyes, feet and kidneys as well as serious problems with the cardiovascular system such as strokes and heart attacks.
Because of the increasing numbers of people with undiagnosed diabetes in the UK the government introduced a large-scale screening programme called NHS health checks. As part of this programme all people aged 40-75 are offered screening tests for diabetes, kidney disease and cardiovascular disease risk. These tests are usually carried out by a GP (doctor).
We know that not all people eligible for these checks have taken up the invitation to have them. There is a significant proportion of the population who do not access healthcare through established routes and may be less likely to visit a GP or may not be registered with a GP at all. It is important that screening tests are made available to everyone.
Community pharmacists are often seen as a first port of call for people seeking medical advice. They provide high street access to the majority of the population who will visit a pharmacy at least once a year. By offering screening tests for diabetes in pharmacies it is hoped that it may make it easier for people who have not had a diabetes test to have one done.
We want to test whether community pharmacies are feasible sites for carrying out diabetes screening. We also want to find out whether a having a fingerpick blood test with the result immediately available means people are more likely to follow up a pharmacists advice to see a GP compared to filling out a questionnaire which assesses diabetes risk without needing to have a blood test.
The aim of this study is to evaluate the level of uptake to further testing in participants who have a positive screening test result at their local pharmacy. Response rates will be compared between the two study groups. Other objectives are to compare the yield (numbers) diagnosed with either diabetes or impaired glucose regulation following a confirmatory test by a GP.

Who can participate?
Participants must be aged 40-75 (35-75 if south Asian due to the increased risk of diabetes), not diabetic, and should not have had a fasting test to screen for diabetes in the previous 12 months.

What does the study involve?
Participants are randomly allocated to one of two groups:
1. Near patient test arm
Once consent has been given, participants will be asked to fill out a questionnaire to assess diabetes risk. Should the participant score 16 points or above they will be immediately be offered a fingerprick test for HbA1c at the pharmacy. If their HbA1c result is greater or equal to 6% (42mmol/l) they will be given a print out of their results and asked to visit their GP for a follow-up test. Regardless of the participants diabetes risk status the results will be sent to their GP with a recommendation on the appropriate course of follow up.
2. Risk score only arm
Once consent has been given, participants will be asked to fill out a questionnaire to assess diabetes risk. Should the participant score 16 points or above they will be given a print out of their results and asked to visit their GP for a follow-up test. Regardless of the participants diabetes risk status the results will again be sent to their GP with a recommendation on the appropriate course of follow up.

What are the possible benefits and risks of participating?
Participants will be able to get screened for diabetes without having to make an appointment with their GP. Some patients may not want their GP to know if they have been diagnosed with diabetes due to implications it may have on employment. This will be made clear to participants before they are asked to give consent.

Where is the study run from?
The study will be run within Leicester, UK.

When is the study starting and how long is it expected to run for?
The study started in March 2011. It is expected that recruitment will be completed in March 2014.

Who is funding the study?
Merck Sharp & Dohme Limited, NHS Leicester City and the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care - Leicestershire, Northamptonshire and Rutland (UK).

Who is the main contact?
Andrew Willis, study coordinator
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Contact information

Type(s)
Scientific

Contact name
Prof Kamlesh Khunti

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LE5 4PW

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Pharmacy based screening of high Risk Individuals using Stepwise Methods: the PRISM study

Acronym
PRISM

Study objectives
The hypothesis to be tested is that screening using a self assessed risk score followed by near patient HbA1c testing in pharmacies will increase uptake of a confirmatory test conducted at the GP surgery compared to screening with a risk score alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Northamptonshire and Rutland Research Ethics Committee 2, 27/07/10

Study design
Two arm individually randomised study with no control (single site)

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Early detection of type 2 diabetes

Interventions
Participants will be individually block randomised to one of two screening arms

Trial arm 1. Near patient test
A paper based version of the Leicester Self-Assessment (LSA) diabetes risk score questionnaire will be given to all individuals who meet the inclusion criteria for the study who are approached at the pharmacy over the recruitment period. Participants with a high LSA risk score (>16 points) randomised to the near patient HbA1c test arm of the study will be immediately offered an appointment with the pharmacist to discuss modifiable risk factors. Following this appointment

the participant will immediately be offered a finger prick NPT HbA1c test in the pharmacy. If the individual presents with a HbA1c above 6% they will be referred to their GP for a confirmatory test.

Trial Arm 2. GP Test method
High risk participants identified by the LSA diabetes risk score questionnaire randomised to the GP test arm will be immediately offered an appointment with the pharmacist to discuss modifiable risk factors. Following this consultation they will be given a letter of referral asking for an HbA1c or fasting plasma glucose (FPG) test to be performed at their general practice. If the individual presents with a HbA1c above 6% or a FPG of 6mmol/l or above they will be asked to re-attend their general practice for a confirmatory test.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Percentage uptake of high risk individuals by a pharmacy test to a confirmatory test at the GP surgery

Primary and secondary outcome data will be extracted via a query of participants medical records by a member of the study team. This will be completed at 3 months post screening appointment.

Key secondary outcome(s))
Number of participants diagnosed with type 2 diabetes and impaired glucose regulation according to the final confirmatory test at the GP surgery

Completion date
01/03/2014

Eligibility

Key inclusion criteria
40-75 years old (35 to 75 if South Asian due to the increased diabetes risk)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Already diagnosed with diabetes
2. Have had a fasting test for diabetes in the previous 12 months performed elsewhere
3. Have a mental impairment, learning difficulty or chronic disease which may impair ability to give informed consent

Date of first enrolment
01/03/2011

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Diabetes Centre
Leicester
United Kingdom
LE5 4PW

Sponsor information

Organisation
University of Leicester (UK)

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp and Dohme

Alternative Name(s)

MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
NHS Leicester City (UK)

Funder Name
The National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care - Leicestershire, Northamptonshire and Rutland (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration