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Diabetes prevention in people from Bangladesh: a pilot trial in East London

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
22/05/2017

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 number of people developing diabetes as adults is growing and in Europe is set to increase by at least 50% in the next 10 years. The problem is particularly intense in people of south Asian origin, where there is 3-6 times the prevalence of type 2 diabetes and the disease presents 10-15 years earlier compared to white Europeans. Based on research in the USA, Finland and India, it is possible to prevent diabetes with a programme of exercise and changes in diet, as well as use of a drug (metformin). The aim of this study is to determine the right methods to test whether this type of programme will be successful in preventing diabetes in people at high risk of the disease in an ethnic minority group, the Bangladeshi community.

Who can participate?
People of Bangladeshi origin aged 20-70 years at high risk of diabetes

What does the study involve?
Participants are randomly allocated to either the control group, who receive standard healthy lifestyle advice, or the behavioural lifestyle intervention group, who receive individual and group advice on diet, exercise and smoking cessation over six fortnightly sessions. Metformin is offered to all participants after 6 months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Institute of Cell and Molecular Science (ICMS) (UK)

When is the study starting and how long is it expected to run for?
June 2005 to October 2012

Who is funding the study?
The Medical Research Council and the Department of Health (UK)

Who is the main contact?
Prof. Graham Hitman
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2007-004283-47

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0624177960

Study information

Scientific Title
Diabetes prevention in people from Bangladesh: a pilot trial in East London

Acronym
BanglaDiP

Study objectives
Current study hypothesis as of 07/05/2013:
To check the feasibility of key aspects of identification of high-risk individuals for diabetes by comparing recruitment using an adapted Cambridge Risk Score (CRS) or a direct screening process using a health examination. 200 high-risk subjects will be randomly allocated to a structured lifestyle intervention or usual care. At six months all participants will have the option

to take metformin. The overall purpose is to generate pilot data that can be used to design a pragmatic and culturally sensitive RCT for diabetes prevention in the local Bangladeshi population.

Study hypothesis amended as of 07/08/2007:
To check the feasibility of key aspects of identification of high-risk individuals for diabetes by comparing recruitment using an adapted Cambridge Risk Score (CRS) or a direct screening process using a health examination. 200 high-risk subjects will be randomly allocated to a factorial design of structured lifestyle intervention and pharmacotherapy using metformin. The overall purpose is generate pilot data that can be used to design a pragmatic and culturally sensitive RCT for diabetes prevention in the local Bangladeshi population.

Study hypothesis provided at time of registration:
Will members of the Bangladeshi population allow recruitment to the testing the tools and be willing to undergo the lifestyle interventions to prevent diabetes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Central Office of Research Ethics Committees (COREC), East London (ref: 05/Q0605/164), approval first granted on 19/01/2006, amendment 1 approved on 26/01/2007
2. New application to COREC South East and Medicines and Healthcare products Regulatory Agency (MHRA) for subsequent phases of the study approved 18/10/2007

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Diabetes

Interventions
Current interventions as of 07/05/2013:
Arm 1: Control Intervention (n=100); will be given standard healthy lifestyle advice.
Arm 2: Behavioural Lifestyle Intervention based on a self-efficacy model (n=100); encompassing

individual and group advice on diet, exercise and smoking cessation over six fortnightly sessions. Metformin 500 mg twice daily (bd) will be offered to all participants at 6 months.

Previous interventions amended as of 07/08/2007:
Arm 1: Control Intervention (n=50); will be given standard healthy lifestyle advice.
Arm 2: Behavioural Lifestyle Intervention based on a self-efficacy model (n=50); encompassiing individual and group advice on diet, exercise and smoking cessation over six fortnightly sessions.
Arm 3: Pharmacotherapy only (n=50); Metformin 500 mg twice daily (bd) will be given to participants as well as standard healthy lifestyle advice.
Arm 4: Both behavioural and pharmacotherapy (n=50).

Interventions provided at time of registration:
Pilot RCT study. To assess recruitment methods and 'risk' data.

Intervention Type
Mixed

Primary outcome measure
Primary outcome measure as of 07/08/2007:
In non-diabetic Bangladeshi participants to test the feasibility of key aspects of identification, recruitment methods, the screening process, interventions and measurement of outcomes for a culturally appropriate RCT to prevent diabetes and subsequent cardiovascular disease.

Previous primary outcome measures:
Cambridge risk score and Finnish score

Secondary outcome measures
Added as of 07/05/2013:
1. Ascertaining the quality of the datasets that can be used to determine risk held in primary care databases and what actions are required to ensure that they are complete
2. Designing, validating and establishing cut-off points for a disease susceptibility risk score to assess whether it is feasible to identify people with the metabolic syndrome in the Bangladeshi community
3. Proportion of eligible people consenting to randomisation (phase 3) and the adherence to or concordance with the intervention by those identified as having metabolic syndrome by direct testing (phase 1) compared to those identified as high risk from the CRS (phase 2)
4. From phase 1 the prevalence of metabolic syndrome, IGT and diabetes in the study population
5. Does venesection impair recruitment?
6. Training manual for lay tutors and a set of SOPs for a future trial
7. Adherence, acceptability and attendance of the behavioural lifestyle intervention
8. Adherence with the study drug in an otherwise well population
9. An approximate indication of changes and variability of possible outcome variables (fasting glucose, waist, weight, BP and conversion to diabetes) in the intervention group as a whole rather than by treatment group.
10. Development and translation of culturally appropriate questionnaires (GHQ12, SF12, modified diabetes IPQ-R and RPAQ) and the feasibility of their use individually and combined in the Bangladeshi community
11. The design of a culturally appropriate RCT of a multi-factorial intervention to prevent diabetes and subsequently cardiovascular disease in the local Bangladeshi community

12. Cost-effectiveness model informing cost data collection in the main trial
13. Judgement about the viability of the main trial with Bangladeshi participants from Tower Hamlets

Overall study start date
01/06/2005

Completion date
12/10/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/05/2013:
For screening strategies, 500 people of Bangladeshi origin aged 20-70 years divided into two groups:
1. Dataset 1 will be invited to have an Oral Glucose Tolerance Test (OGTT) and fasting lipid profile and then if at high risk of diabetes invited to intervention
2. Dataset 2 will be identified as high risk from GP records and then invited directly for intervention

Previous inclusion criteria:
500 subjects of Bangladeshi origin aged 20-65 years divided randomly into two groups, dataset 1 being invited to have an Oral Glucose Tolerance Test (OGTT) and fasting lipid profile.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Target number of participants for intervention as of 07/08/2007: 200; Target number of participants for screening provided at time of registration: 500

Key exclusion criteria
Added as of 07/08/2007:
1. Outside age range
2. Major co-morbidity including cardiovascular disease, diabetes and cancer
3. Contra-indications to metformin

Date of first enrolment
01/06/2005

Date of final enrolment
12/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Cell and Molecular Science (ICMS)
London
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E1 2AT

Sponsor information

Organisation
Queen Mary, University of London (UK)

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Sponsor type
University/education

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http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (G0501284)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
UK Department of Health (DH) Excess Treatment Costs

Funder Name
North East London Consortium for Research and Development (NELCRAD) (UK) (funded the pre-pilot studies)

Funder Name
NHS Research and Development Support Funding (UK) (funded the pre-pilot studies)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration