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Prevention of type 2 diabetes in HIV: a pilot study of effectiveness and acceptability

Submission date
30/01/2014

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The risk of HIV patients developing diabetes has been reported to be up to four times higher compared to those without HIV. Lifestyle modifications can prevent type 2 diabetes in the general population; given the differences in the cause of diabetes in HIV, and potential HIV-specific barriers to lifestyle change, it is important to develop effective methods in this population. Therefore, this study aims to find out an effective lifestyle intervention for treating diabetes in HIV.

Who can participate?
The study is open to people living with HIV registered as patients at Guy's and St Thomas' Hospital in London, UK

What does the study involve?
Part 1: In this comparison study, 162 participants grouped according to blood glucose levels have factors associated with type 2 diabetes studied.
Part 2: In this initial study up to 46 patients with insulin resistance receive 6 months of advice to change diet and physical activity. Change in insulin resistance is measured.
Part 3: Participants are interviewed to assess the acceptability of the intervention, and describe what helps and what hinders lifestyle change.
Part 4: Two focus groups of 6-10 participants discuss findings to aid the design of a future large-scale study.

What are the possible benefits and risks of participating?
Participants with pre-diabetes are eligible to take part in a 6-month intervention aiming to reduce their risk of developing diabetes; however, this is an initial study and the degree of potential success is not yet known. Participants in the study will help define risk factors for developing type 2 diabetes.

Where is the study run from?
Guy's and St Thomas' Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2013 to August 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Mr Alastair Duncan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15786

Study information

Scientific Title
Prevention of type 2 diabetes in HIV: a pilot study of effectiveness and acceptability: a non-randomised controlled trial

Acronym
STOP Diabetes

Study objectives

1. Can individualised lifestyle advice reduce insulin resistance in HIV patients with pre-diabetes?
2. Is this advice acceptable to participants?
3. Are barriers to lifestyle change HIV-specific?

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/1543; First MREC approval date 11/11/2013

Study design
Non-randomised; Interventional; Design type: Prevention, Treatment

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network, Infection; Subtopic: Type 2, Infection (all Subtopics); Disease: Diabetic Control, Infectious diseases and microbiology, Education

Interventions
Lifestyle advice, 6 months of individualised diet and physical activity advice; Follow Up Length: 6 month(s); Study Entry : Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in insulin resistance; Timepoint(s): Measured by frequently sampled liquid meal tolerance test at Day 1 and Day 180

Secondary outcome measures

1. Blood pressure; Timepoint(s): day 1 and day 180
2. Change in anthropometry; Timepoint(s): day 1 and day 180
3. Change in dietary intake; Timepoint(s): day 1 and day 180
4. Change in lipids; Timepoint(s): day 1 and day 180
5. Change in physical activity; Timepoint(s): day 1 and day 180
6. Quality of life; Timepoint(s): day 1 and day 180

Overall study start date
23/12/2013

Completion date
27/08/2015

Eligibility

Key inclusion criteria
Part 1:
1. HIV positive adults aged 18 years
2. Are competent in English language

Part 2:
1. HIV positive adults aged 18 years old
2. Stable on current antiretrovirals for last 6 months
3. Unlikely to need to change their antiretrovirals within the next 6 months
4. Have insulin resistance (fasting glucose 5.6 - 6.9 mmol/l)
5. Able to give informed consent
6. Willing and able to participate in an exercise programme
7. Able to attend monthly appointments for 6 months
8. In the opinion of the investigator will be unlikely to have any planned events within the next 6 months that would prevent adherence to a lifestyle change programme
9. Competent in English language

Part 3:
1. Those exiting Part 2 after completing the 6 month intervention
2. Those who withdraw from Part 2 after the initial visit and before completing the 6 month intervention
3. Those who were eligible for Part 2, declined the intervention, but consented to interview

Part 4:
1. HIV positive expert patient or patient representative, or an HIV advocate
or
2. Health professional working in HIV care

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Planned Sample Size: 162; UK Sample Size: 162

Total final enrolment
28

Key exclusion criteria
Part 1:
1. Unable to attend for a single visit
2. Type 1 diabetes

Part 2:
1. Have a clinical diagnosis of type 1 or type 2 diabetes
2. Have a fasting glucose indicative of diabetes (=7.0 mmol /l)
3. Have a random glucose indicative of diabetes (=11.1 mmol/l)
4. Are pregnant, planning for a pregnancy, or lactating
5. Are naive to antiretroviral therapy
6. Have medical problems that may interfere with patient safety
7. Have a current medical condition that makes exercise inadvisable
8. Are fitted with an artificial cardiac pacemaker device
9. Have liver impairment suggested by liver function tests (ALT) within the last year elevated =2.
5 times above the upper level of the laboratory reference range
10. Have hepatitis B and/or C coinfection
11. Use medicines that might interfere with glucose homeostasis measures, e.g. corticosteroids, anabolic steroids, testosterone or diabetes medications

Part 3:
1. Are unable to undertake the interview within two weeks of withdrawing/completing, as beyond this time the participants history may change as elements are forgotten.

Part 4:
1. Are unable to attend a single focus group

Date of first enrolment
23/12/2013

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas's Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation trust (UK)

Sponsor details
Asthma Allery & Respiratory science
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
NIHR Doctoral Research Fellowship; Grant Codes: CDRF-2012-03-021

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	15/10/2020	Yes	No
HRA research summary			28/06/2023	No	No