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An intervention to examine the effect of vitamin D on urine protein levels in type 2 diabetes

Submission date
10/04/2017

Recruitment status
No longer recruiting

Registration date
07/06/2017

Overall study status
Completed

Last Edited
19/04/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a long term condition where a person is unable to control their blood sugar (glucose) levels as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). Diabetic kidney disease (nephropathy) develops in nearly 40% of patients with type 2 diabetes (T2DM). Diabetic nephropathy is caused by damage to the tiny blood vessels in the kidneys due to uncontrolled blood sugar levels, which mean that the kidneys become less effective at filtering urine. This is associated with albuminuria (protein in the urine). Treatment with some drugs reduces the loss of albumin through the urine and delays disease progression. There is increasing evidence that vitamin D could also be important in management of diabetic kidney disease. The aim of this study is to investigate the efficacy and safety of a combined regimen of calcitriol (active vitamin D) and established drugs for diabetic kidney disease

Who can participate?
Type 2 diabetic adults with albuminuria

What does the study involve?
Participants are randomly allocated to one of two groups. All participants are being treated with medication to control their blood pressure. Those in the first group receive this usual treatment only, and those in the second group are also treated with additional vitamin D tablets for 26 weeks. At the start of the study and then after 26 weeks, participants provide urine samples to assess the amount of protein in their urine as well as tests to assess how well they are controlling their diabetes and general health.

What are the possible benefits and risks of participating?
Participants benefit from receiving regular contact with the research team which could improve the effectiveness of their condition. The risks associated with taking part in this study are minimal as the study uses methods and approaches that are already used daily in clinical practice to care for patients with diabetic kidney disease. Also, there will be close follow-up in the clinic with specific advice to avoid any potential problems.

Where is the study run from?
Hamad Medical Corporation (Qatar)

When is the study starting and how long is it expected to run for?
April 2017 to April 2018

Who is funding the study?
Qatar National Research Fund (Qatar)

Who is the main contact?
1. Professor Shahrad Taheri (scientific)
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2. Dr Muhammad Asim (scientific)

Contact information

Type(s)
Scientific

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT03216564

Secondary identifying numbers
1400039

Study information

Scientific Title
Intervention using vitamin D for Elevated urinary ALbumin in diabetes (IDEAL-2)

Acronym
IDEAL-2

Study objectives
Active vitamin D (1,25-dihydroxycholecalciferol (calcitriol), added to inhibition of the renin angiotensin aldosterone system (RAAS), via angiotensin converting enzyme inhibition or angiotensin receptor blockade, results in superior reduction in urine albumin excretion in type 2 diabetes mellitus (T2DM) compared to RAAS inhibition alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Weill Cornell Medicine, Qatar Institutional Review Board, 09/01/2017, ref: 14-00039
2. Hamad Medical Corporation, Qatar, Institutional Review Board, 23/06/2016, ref: 16235/16

Study design
Single-centre open-label randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Diabetic nephropathy

Interventions
Enrolled subjects, who are clinically optimised with an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB), will be randomised to one of two groups.

Usual Care: Participants are treated with ACEI/ARB alone for 26 weeks.

Intervention Group: Participants are treated with ACEI/ARB AND active vitamin D (Calcitriol) 0.25 micrograms orally per day for 26 weeks.

Participants are followed up after 26 weeks.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Calcitriol

Primary outcome measure
Urinary albumin creatinine ratio (ACR) measured biochemically at baseline and 26 weeks

Secondary outcome measures
1. 24-hour urine albumin (24h UA) excretion is measured biochemically at baseline and 26 weeks
2. Estimated glomerular filtration rate (eGFR) calculated using the Modification of Diet in Renal Disease (MDRD) equation at baseline and 26 weeks
3. Blood pressure is measured using a digital sphygmomanometer at baseline and 26 weeks

Tertiary outcome measures
1. Anthropometry and body composition measures are completed using Tanita bioimpedance scales at baseline and 26 weeks
2. Diabetes control is measured biochemically using glycated haemoglobin at baseline and 26 weeks
3. Cardiovascular function is assessed by measuring arterial stiffness using the Vicorder device at baseline and 26 weeks
4. Diabetic eye disease incidence is measured using retinal photographyat baseline and 26 weeks
5. Diabetic neuropathy incidence is measured using a diabetic neuropathy questionnaire and clinical examination at baseline and 26 weeks
6. Autonomic nervous system function is measured at baseline and 26 weeks
7. Obstructive sleep apnoea incidence is measured using the apnoea-hypopnoea index at baseline and 26 weeks
8. Sleepiness is measured using the Epworth Sleepiness Scale at baseline and 26 weeks
9. Quality of life is measured using the EQ5D questionnaire at baseline and 26 weeks

Overall study start date
10/05/2016

Completion date
10/05/2019

Eligibility

Key inclusion criteria
1. Age greater than or equal to 18 years and less than 80 years
2. Diagnosis of T2DM requiring treatment with at least one oral hypoglycaemic medication or insulin
2.1. Subjects will be considered to have established T2DM if the diagnosis of diabetes has been made and the subjects were treated with insulin or an oral hypoglycaemic agent for at least 6 months after diagnosis
2.2. Subjects will be considered to have newly established T2DM if the diagnosis of diabetes was diagnosed with a fasting plasma glucose ≥ 7 mmol/L (126 mg/dL) or haemoglobin A1c is >6.5% in the past 6 months
3. Documented albuminuria defined as a presence of albuminuria on two occasions in the last six months:
3.1. Albumin ≥ 30 mg/24 hour in a 24 hour urine collection, or
3.2. Albumin ≥ 20 µg/min in a short-time urine collection, or
3.3. Albumin ≥ 30 mg/L in a spot urine sample, or
3.4. A spot-urine albumin-creatinine ration (ACR) ≥ 30 mg/g creatinine (≥ 2.5 mg/mmol creatinine in men, ≥ 3.5 mg/mmol creatinine in women)
4. Estimated glomerular filtration rate (eGFR) using the 4-variable Modification of Diet in Renal Disease (MDRD) equation of ≥ 25 mL/min/1.73 m2

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
320

Key exclusion criteria
1. If female, positive pregnancy test or planning pregnancy in the subsequent 12 months
2. Pregnant
3. Breastfeeding
4. Corrected serum calcium ≥ 2.62 mmol/L
5. Serum Potassium > 5.2 mmol/L if not on ACEI or ARB; Serum Potassium > 6.0 mmol/L if on ACEI or ARB
6. 25-hydroxyvitamin D (25-OH Vit D) > 80 ng/mL
7. PTH > 200 pg/mL
8. Poorly controlled hypertension defined as systolic blood pressure ≥ 180 mm Hg or diastolic blood pressure ≥ 110 mm Hg
9. Systolic blood pressure (SBP) ≤ 110 mm Hg
10. History of kidney stones

11. History of severe chronic disease (e.g. chronic liver disease)
12. Active malignancy
13. Recent diagnosis of acute renal failure within 3 months of screening visit
14. Likelihood of renal replacement therapy within 1 year

Date of first enrolment
10/04/2017

Date of final enrolment
10/10/2018

Locations

Countries of recruitment
Qatar

Study participating centre
Hamad Medical Corporation
Al Rayyan Road
Doha
Qatar
24144

Sponsor information

Organisation
Hamad Medical Corporation

Sponsor details
Hamad General Hospital
Doha
Qatar
3050

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02zwb6n98

Funder(s)

Funder type

Research organisation

Funder Name
Qatar National Research Fund

Alternative Name(s)
, QNRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Qatar

Results and Publications

Publication and dissemination plan
Planned publication of findings in a high-impact peer reviewed journal.

Intention to publish date
01/05/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/04/2018		Yes	No