

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 07/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/04/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Shahrads Taheri (scientific)
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2. Dr Muhammad Asim (scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT03216564

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 photography at 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

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 μ g/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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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

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