Steno Diabetes Center Copenhagen

General information

Full title of the trial	The ZIRCUS study - A randomized, double-blind, placebo controlled, parallel, multicenter study of the effects of 12-weeks of sodium zirconium cyclosilicate (Lokelma) on albuminuria (UACR) in patients with diabetes and hyperkalemia
EudraCT no.	2019-000595-42
Study type	Interventional
Study type	Randomised, placebo-controlled, parallel, double blinded
Intervention	Drug: Sodium zirconium cyclosilicate 5 g, powder for oral suspension Drug: Placebo, powder for oral suspension
Enrolment	9
Start date	November 26, 2019
Study termination date	April 19, 2022
Reason for early termination	The study was prematurely ended due to slow enrolment.

Sponsor:

Organisation name	Steno Diabetes Center Copenhagen
Street Address	Borgmester Ib Juuls Vej 83
Post Code	2730
Town/city	Herlev
Country	Denmark

Contact:

Name of organisation	Steno Diabetes Center Copenhagen
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Population

Recruitment details	The study was conducted at to investigational centers, one in Denmark (Steno Diabetes Center Copenhagen) and one in Sweden (Akademiska Sjukhuset Uppsala)
Subjects per country	Denmark: 8, Sweden: 1

Participant flow	All	Sodium zirconium cyclosilicate 5 g	Placebo
Enrolled	9	4	5
Randomised	9	4	5
Started treatment	8	3	5
Completed	7	2	5
Not completed	2	2	0
Reason not completed			
Non-compliance	1	1	0
Withdrawal by subject	1	1	0

Results

Nine male participants were enrolled in the study.

No results can be reported from the study.

Adverse events

Time frame for collecting adverse events were from randomisation to end of study.

Serious adverse events	Sodium zirconium cyclosilicate 5 g	Placebo
Subjects exposed	3	5
Number of serious adverse events	2	1
Number of subjects affected by serious adverse events	1	1
Number of deaths (all causes)	0	0
Number of deaths resulting from adverse events	0	0
Number of serious adverse events		
Gastrointestinal disorders		
Diverticulitis	1	
Metabolism disorders		
Hyperkalemia		1
Renal and urinary disorders		
Acute kidney injury	1	

Non-serious adverse events	Sodium zirconium cyclosilicate 5 g	Placebo
Subjects exposed	3	5
Number of non-serious adverse events	2	7
Number of subjects affected by non-serious adverse events	2	3
Number of non-serious adverse events		
Cardiac disorders		
Sinus arrythmia	1	
Gastrointestinal disorders		
Constipation	1	
General disorders		
Weight gain		1
Injury		
Fall accident		1
Musculoskeletal disorders		
Muscle pain		1
Respiratory disorders		
Cough		1
Skin disorders		
Rash		2
Skin ulcer		1