Randomized, double-blind, placebo-controlled crossover trial assessing the impact of the SGLT2 inhibitor empagliflozin on urinary supersaturations in kidney stone formers (SWEETSTONE)

First published: 14/10/2021

Last updated: 17/09/2025

Study Finalised

Administrative details

EU PAS number

EUPAS43690

Study ID

49154

DARWIN EU® study

No

Study countries

☐ Switzerland

Study description

Kidney stones are a global healthcare problem. Given the high recurrence rate, the morbidity related to symptomatic stone disease and the enormous healthcare expenditures and indirect cost associated with kidney stones, an effective medical prophylaxis is clearly an unmet need. Explanatory analyses of randomized controlled trials with sodium/glucose co-transporter isoform 2 (SGLT2) inhibitors indicated a 30-50% reduced rate of stone events in patients with diabetes, but the underlying mechanisms remain unclear. We aim to determine the effect of empagliflozin, the best-characterized SGLT2 inhibitor to date, on urinary supersaturations in non-diabetic kidney stone formers to evaluate their therapeutic potential for recurrence prevention.

Study status

Finalised

Research institutions and networks

Institutions

Inselspital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Fuster

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/11/2020

Study start date

Actual: 25/08/2021

Date of final study report

Planned: 30/06/2023

Actual: 28/04/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim (Schweiz) GmbH, Inselspital Bern, Switzerland (intramural)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Other study registration identification numbers and links

ClinicalTrials.gov: NCT04911660

Kofam: SNCTP000004272

Publication study report

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Clinical trial

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

The purpose of this study is to evaluate whether empagliflozin lowers urinary supersaturations as compared to placebo in participants with at least one past episode of kidney stone passage (either spontaneous or removed by urologic intervention).

Study Design

Clinical trial randomisation

Randomised clinical trial

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A10BK03) empagliflozin

empagliflozin

Medical condition to be studied

Nephrolithiasis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

Study design details

Outcomes

The primary objective will be addressed by evaluating three primary outcomes. Each of these outcomes will be assessed separately as they reflect different mechanisms and are of potential (clinical) relevance for later trials. • Calcium oxalate supersaturation, • Brushite (calcium phosphate) supersaturation, and • Uric acid supersaturation. Blood: Na, K, Cl, Ca, Mg, P, osmolality, glucose, albumin, creatinine, urea, uric acid, blood gas analysis, 25 hydroxy and 1,25 dihydroxy vitD, PTH, FGF23, HbA1c, lipid panel, TSH. 24 h urine: Na, K, Cl, Ca, Mg, P, osmolality, glucose, protein, albumin, creatinine, urea, uric acid, oxalate, citrate, sulfate, ammonia, bicarbonate, pCO2, pH, calcium

Data analysis plan

Linear mixed effects model will be used for analysis. The mixed effects model will contain the baseline measurements, the 14-days measurements, and an indicator for the treatment and period as fixed effects to adjust for any period effects, and a random effect for participants to account for within-participant correlation of repeated measurements. All primary and secondary endpoints will be analyzed with this approach.

Documents

Study report

Study publications

Publication of study results

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No