

Effect of Edoxaban on Laboratory assays

H. von HORN 1, 2, L. BUI 3, A. RASMUSON 1, 2, J. DOUXFILS 4, J. HARENBERG 5, 6, J. ANTOVIC 1, 2, K. CHRISTENSEN 3

- ¹ Division of Clinical Chemistry, Karolinska University Hospital, Stockholm, Sweden, ² Department of Molecular Medicine and Surgery, Karolinska Institutet, Stockholm, Sweden, ³ Department of Clinical Chemistry Central Hospital Karlstad, Karlstad, Sweden, ⁴ University of Namur, Department of Pharmacy, Namur, Belgium,
- ⁵ Heidelberg University, Heidelberg, Germany, ⁶ DOASENSE GmbH, Heidelberg, Germany

INTRODUCTION

Direct acting oral anticoagulants are being increasingly prescribed. Edoxaban is a factor Xa-inhibitor expected to increase especially in patients with active cancer.

Even though routine determination of DOAC concentration is in general not considered necessary, the increased use of DOACs, also in a elderly and frail population means that the need for DOAC measurements may be increasing.

DOAC measurements may be relevant to control exposure in patients with decreased kidney or liver function but also in patients needing acute interventions like thrombolysis or surgery.

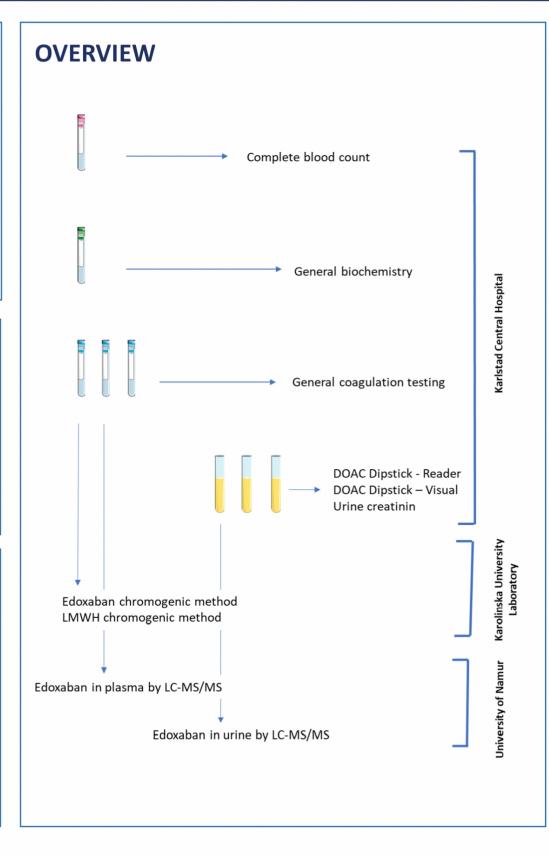
AIM

- The general aim of the proposed study is to determine the effect of edoxaban on laboratory assays,
- both non-DOAC specific general coagulation assays, as well as specific assays, including a POCT-method (DOAC Dipstick, DOASENSE, GmbH).
- The ability to exclude significant edoxaban concentration in relation to turn around time will be investigated

METHODS

Plasma and urine samples have been collected from patients treated with edoxaban at different time points in relation to last intake of medication Edoxaban activity in plasma will be determined by chromogenic methods calibrated against edoxaban as well as LMWH

Urine anti-factor Xa activity will be determined in urine by DOAC Dipstick Edoxaban concentration, including the presence and concentration of the edoxaban parent compound, as well as the M4 metabolite will be measured by LC-MS/MS in plasma and urine



PRELIMINARY RESULTS

To date, June 30, 2021 43 patients have been included.

General biochemistry and standard coagulation assays, as well as POCT - DOAC Dipstick by visual and reader analysis have been performed.

Next step is to send samples for testing by chromogenic methods and LC-MS/MS.

Age (years) mean +/- SD	64,2 +/- 7,9
Sex, n (%)	
Female	16 (37,2 %)
Male	27 (62,8 %)
BMI (kg/m2) mean +/- SD	27,1 +/- 3,6
Creatinin (mmol/L) mean +/- SD	81,4 +/- 19,1

Table: Baseline characteristics of patients enrolled this far

ANTICIPATED RESULTS

We anticipate that the result of the study will generate information on the effect of edoxaban on general coagulations assays, as well as specific edoxaban assays and the differential sensitivity of these assays to the major edoxaban metabolite.

The study will also provide guidance on safe practices for rapid exclusion of clinically relevant edoxaban activity in urine which will be of benefit to accelerate medical decision making in emergency situations.

CONFLICT OF INTEREST

Prof. Dr Harenberg is managing director of DOASENSE.

MSD Organon are providing financial support of the study.

Othervise no relevant COI.

CONTACT INFORMATION

Henrik von Horn, MD, PhD: henrik.vonhorn@sll.se

Kjeld Christensen, MD, PhD: kjeld.christensen@regionvarmland.se